EXHIBIT B

(DEFENDANTS' EXHIBIT LIST)

Defendants' Trial Exhibits Wolfe

Exhibit No.	Description
1001	Records of Aring Neurology, Cincinnati
1002	Records of Asthma Allergy Immunology Center/Phem Menom MD, Baton Rouge
1003	Records of Atwell MD, Bernard, Pensacola
1004	Records of Baptist Medical Center, Jacksonville
1005	Records of Baton Rouge Cardiology Center/Henry Patrick MD
1006	Records of Baton Rouge Clinic
1007	Records of Baton Rouge Orthopedic Clinic
1008	Records of Baton Rouge Urology Clinic
1009	Records of Boston's Children's Hospital
1010	Records of Boston's Children's Hospital - Radiology
1011	Records of Boston's Children's Hospital – Pathology Department (slides only – no paper records)
1012	Records of Cincinnati Children's Hospital
1013	Records of Cincinnati Children's Hospital (supplemental)
1014	Records of Daniel MD, Charles/Pediatric Medical Center, Baton Rouge
1015	Records of Dermatology Clinic/Loyd Frye MD
1016	Records of Dillard MD, Robert, Pensacola
1017	Records of Ear, Nose & Throat Medical Center/Earl Garitty MD/Charles LeBlanc MD, Baton Rouge
1018	Records of East Jefferson General Hospital
1019	Records of Hall MD, Shelley/Island Pediatrics, Orange Park FL
1020	Records of Hancock Medical Center, Bay St. Louis MS
1021	Records of Honigman Pediatric Clinic
1022	Records of LaFranca MD, Ann, Baton Rouge
1023	Records of Mid Coast Hospital. Brunswick ME
1024	Records of Mulla MD, Omar/Martin's Point Health Care, Brunswick ME
1025	Records of Nemours Children's Clinic, Jacksonville FL
1026	Records of Northshore Regional Medical Center, Slidell LA
1027	Records of Orange Park Medical Center, Orange Park FL
1028	Records of Our Lady of the Lake Regional Medical Center, Baton Rouge
1029	Records of Our Lady of the Lake Regional Medical Center, Baton Rouge - Radiology
1030	Records of Pearl Acres Pediatrics/Cherie Oertling MD, Slidell LA
1031	Records of Poche MD, William, Baton Rouge
1032	Records of Proctor MD, Allan/The Neuromedical Center Clinic, Baton Rouge
1033	Records of Sacred Heart Hospital Emerald Coast, Destin FL
1034	Records of Sacred Heart Hospital, Pensacola
1035	Records of Sacred Heart Hospital, Pensacola - Radiology
1036	Records of Sacred Heart Hospital, Pensacola (supplemental)
1037	Records of Scott, Owen PhD, Baton Rouge
1038	Records of Slidell Memorial Hospital
1039	Records of St. Francis Cabrini Hospital
1040	Records of Tulane Hospital for Children, New Orleans
1041	Records of UAMS, Little Rock
1042	Records of University Hospital, Cincinnati
1043	Records of University Hospital, Cincinnati - Radiology
1044	Records of University Neurology, Cincinnati
1045	Records of University of Cincinnati, Division of Digestive Disease
1046	Records of Zuckerman MD, Steven, Baton Rouge
1047	Records of Louisiana Cardiology Associates/Carl Luikart MD, Baton Rouge

1048	Records of Digestive Health Center of Louisiana/John Walker McDonald MD, Baton Rouge
1049	Insurance records
1050	Curriculum Vitae of Hiral Patel
1051	Curriculum Vitae of Adrian Thomas
1052	Curriculum Vitae of Dana Volpe
1053	Curriculum Vitae of Anthony R. Temple
1054	Curriculum Vitae of Ardith Talbott
1055	Curriculum Vitae of Ashley McEvoy
1056	Curriculum Vitae of Cathy Gelotte
1057	Curriculum Vitae of Douglas Hough
1058	Curriculum Vitae of Edward Nelson
1059	Curriculum Vitae of Eileen Helzner
1060	Curriculum Vitae of Gerald Krueger
1061	Curriculum Vitae of Hina Harlow
1062	Curriculum Vitae of John Zone
1063	Curriculum Vitae of Kenneth Kwong
1064	Curriculum Vitae of Laura Reel Plantz
1065	Curriculum Vitae of Lynn Pawelski
1066	Curriculum Vitae of Margarita Gardiner
1067	Curriculum Vitae of Mary Joan Denisco
1068	Curriculum Vitae of Michelle Miller
1069	Curriculum Vitae of Paula Oliver
1070	Curriculum Vitae of Richard Vezina
1071	Curriculum Vitae of Samuel Lesko
1072	Curriculum Vitae of Sandra Schoenewald
1073	Curriculum Vitae of Steven Silber
1074	Curriculum Vitae of Tiziana Fox
1075	Curriculum Vitae of Willie Pagsuyuin
1076	Plaintiff's First Request for Production of Documents Directed to Defendant McNeil Consumer Healthcare, A Division of McNEIL-PPC, Inc. (served 5/29/2007)
1077	Plaintiff's First Request for Production of Documents Directed to Defendant Johnson & Johnson (served 10/19/2007)
1078	Plaintiff's First Set of Interrogatories Directed to Defendant McNeil Consumer Healthcare, A Division of McNEIL-PPC, Inc. (served 5/29/2007)
1079	Plaintiff's First Set of Interrogatories Directed to Defendant Johnson & Johnson (served 10/19/2007)
1080	Plaintiff's Supplemental Interrogatories and Document Request Directed to Defendants McNeil Consumer Healthcare, A Division of McNEIL-PPC, Inc., and Johnson & Johnson (served 4/10/2008)
1081	McNeil's Response to Plaintiff's First Request for Production (served 7/5/2007)
1082	Johnson & Johnson's Response to Plaintiff's First Request for Production (served 12/10/2007)
1083	McNeil's Response to Plaintiff's First Set of Interrogatories (served 7/5/2007)
1084	McNeil's Amended Response to Plaintiff's First Set of Interrogatories (served 9/4/2007)
1085	McNeil's Supplemental Response to Plaintiff's First Set of Interrogatories and Response to Plaintiff's Revised Interrogatory Numbers 21 and 42 (served 10/30/2007)
1086	Johnson & Johnson's Response to Plaintiff's First Set of Interrogatories (served 12/10/2007)
1087	Defendants McNeil Consumer Healthcare, A Division of McNEIL PPC, and Johnson & Johnson's Responses to Plaintiff's Supplemental Interrogatories and Document Request (served 5/16/2008)
1088	Defendant McNeil Consumer Healthcare's First Set of Interrogatories to Plaintiff Kiley Wolfe (served 3/20/2007)

1089	Defendant McNeil Consumer Healthcare's First Request for Production to Plaintiff Kiley Wolfe (served 3/20/2007)
1090	Plaintiff's Responses to Defendant McNeil Consumer Healthcare's First Set of Interrogatories (served 5/18/2007)
1091	January 11, 2008 Letter from Plaintiff's Counsel Supplementing Plaintiff's Responses to Defendant McNeil Consumer Healthcare's First Set of Discovery Requests
1092	Plaintiff's Supplemental Responses to Defendant McNeil Consumer Healthcare's First Set of Interrogatories (served 1/7/2010)
1093	Plaintiff's Supplemental Answer to Interrogatory No. 7 (served 10/1/2010)
1094	Plaintiff's Responses to Defendant McNeil Consumer Healthcare's First Request for Production of Documents (served 5/18/2007)
1095	Plaintiff's Supplemental Responses to Defendant McNeil Consumer Healthcare's First Request for Production of Documents (served 1/7/2010)
1096	October 22, 2007 Letter from Plaintiff's Counsel Supplementing Plaintiff's Answers to McNeil's First Request for Production of Documents
1097	August 5, 2009 Letter from Plaintiff's Counsel Supplementing Plaintiff's Answers to Defendant's Request for Production of Documents
1098	December 20, 2007 Letter from Plaintiff's Counsel Supplementing Plaintiff's Discovery Responses
1099	February 15, 2008 Letter from Plaintiff's Counsel Supplementing Plaintiff's Discovery Responses
1100	March 28, 2008 Letter from Plaintiff's Counsel Supplementing Plaintiff's Discovery Responses
1101	December 31, 2009 Letter from Plaintiff's Counsel Supplementing Plaintiff's Discovery Responses, Including Providing Janet Leland's Day Planner
1102	Defendant McNEIL-PPC, Inc.'s Interrogatories to Plaintiff Kiley Wolfe (served 8/26/2008)
1103	Defendant Johnson & Johnson's Interrogatories to Plaintiff Kiley Wolfe (served 8/26/2008)
1104	Defendant Johnson & Johnson Pharmaceutical Research and Development, LLC's Interrogatories to Plaintiff Kiley Wolfe (served 8/26/2008)
1105	Plaintiff's First Set of Interrogatories Directed to William Weldon (served 11/23/2010)
1106	Plaintiff's First Set of Interrogatories Directed to Colleen Goggins (served 11/23/2010)
1107	Responses to Plaintiff's First Set of Interrogatories Directed to William Weldon (served 12/27/2010)
1108	Responses to Plaintiff's First Set of Interrogatories Directed to Colleen Goggins (served 12/27/2010)
1109	Plaintiff's Federal Rule 26(a) Disclosures with Attachments (served 3/29/2007)
1110	Plaintiff's Amended Rule 26(a) Disclosures (served 11/9/2010)
1111	Defendants' Initial Disclosures (served 4/2/2007)
1112	Defendants' Answer to Complaint (February 21, 2007)
1113	Complaint and Jury Demand (filed 1/26/2007)
1114	Janet Leland's Day Planner (Exhibit L to Deposition of Janet Leland)
1115	Photographs of Kiley Wolfe
1116	Exhibit 3 to Deposition of Maureen Jonas, M.D.
1117	Exhibit C to Deposition of Maya Srivastava, M.D.
1118	Exhibit H to Deposition of Maya Srivastava, M.D.
1119	Exhibit 2 to Deposition of Richard Vezina
1120	Exhibit 3 to Deposition of Richard Vezina
1121	Exhibit 5 to Deposition of Richard Vezina
1122	Exhibit 6 to Deposition of Richard Vezina
1123	Exhibit 7 to Deposition of Richard Vezina
1124	Exhibit 12A to Deposition of Richard Vezina
1125	Exhibit 12B to Deposition of Richard Vezina
1126	Exhibit 16 to Deposition of Richard Vezina

1127	Exhibit 18 to Deposition of Richard Vezina
1128	Exhibit 19 to Deposition of Richard Vezina
1129	Exhibit 21 to Deposition of Richard Vezina
1130	Exhibit 23 to Deposition of Richard Vezina
1131	Kiley Wolfe Adverse Event Files (Bates Ranges MOT00015848 – MOT00015872, MOT00025626 – MOT00025289, MOT00523088, MC074035, MC074039, MC074042)
1132	Motrin Packaging
1133	All invoices and billings records for all plaintiff's experts in all ibuprofen litigation
1134	Nelson's Textbook of Pediatrics 2000 (16th ed.)
1135	Nelson's Textbook of Pediatrics 1996 (15th ed.)
1136	Nelson's Textbook of Pediatrics 2007 (18th ed.)
1137	Nelson's Textbook of Pediatrics 2004 (17th ed.)
1138	MedWatch Report files of Kiley Wolfe
1139	Top 200 OTC/HBC brands in 2000-2007, information compiled by Information Resources, Inc., Chicago - ARE 232-234
1140	Top 200 Generic Drugs by Units in 200-2007, information compiled by Information Resources, Inc., Chicago
1141	Top 200 Generic Drugs by Retail Dollars in 2000-2007, information compiled by Information Resources, Inc., Chicago
1142	Report of Plaintiff's Expert Talal Chatila, M.D.
1143	Report of Plaintiff's Expert Robert C. Nelson, Ph.D.
1144	Report of Plaintiff's Expert Philip Rosenthal, M.D.
1145	Report of Plaintiff's Expert Manuela G. Neuman, Ph.D.
1146	Report of Plaintiff's Expert Moshe Arditi, M.D.
1147	Report of Plaintiff's Expert Eric Pierce, M.D., Ph.D.
1148	Report of Plaintiff's Expert Randall Tackett, Ph.D.
1149	Report of Plaintiff's Expert Jonathan E. Walker, M.D.
1150	Report of Plaintiff's Expert William Bruce Jones, Ph.D.
1151	Report of Plaintiff's Expert Steven Pliskow, M.D.
1152	Report of Plaintiff's Expert James B. Hoyme, M.D.
1153	Report of Plaintiff's Expert Marvin E. Goldberg, Ph.D.
1154	Report of Plaintiff's Experts Royal A. Bunin, MBA, and David T. Bunin, FSA
1155	Report of Plaintiff's Expert George M. Samaras, Ph.D.
1156	Report of Plaintiff's Expert Laura Bix, Ph.D.
1157	Report of Plaintiff's Expert Lorraine E. Buchanan, RN
1158	Report of Plaintiff's Expert Roger E. Salisbury, M.D.
1159	Curriculum Vitae of Plaintiff's Expert Talal Chatila, M.D.
1160	Curriculum Vitae of Plaintiff's Expert Robert C. Nelson, Ph.D.
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1175	Curriculum Vitae of Plaintiff's Expert Roger E. Salisbury, M.D.
1176	All documents disclosed and relied upon by Plaintiff's Expert Talal Chatila, M.D.
1177	All documents disclosed and relied upon by Plaintiff's Expert Robert C. Nelson, Ph.D.
1178	All documents disclosed and relied upon by Plaintiff's Expert Philip Rosenthal, M.D.
1179	All documents disclosed and relied upon by Plaintiff's Expert Manuela G. Neuman, Ph.D.
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1193	Invoices of Plaintiff's Expert Talal Chatila, M.D.
1194	Invoices of Plaintiff's Expert Robert C. Nelson, Ph.D.
1195	Invoices of Plaintiff's Expert Philip Rosenthal, M.D.
1196	Invoices of Plaintiff's Expert Manuela G. Neuman, Ph.D.
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1208	Invoices of Plaintiff's Expert Lorraine E. Buchanan, RN
1209	Invoices of Plaintiff's Expert Roger E. Salisbury, M.D.
1210	Defendants' Rule 26(A)(2) Expert Disclosure and Reports (served 5/17/2010)
1211	Report of Defendants' Expert Margaret C. Fisher, M.D.
1212	Report of Defendants' Expert M. Laurentius Marais, Ph.D.
1213	Report of Defendants' Expert Maja Mockenhaupt, M.D., Ph.D.
1214	Report of Defendants' Expert Louis A. Morris, Ph.D.
1215	Report of Defendants' Expert Elizabeth B. Rand, M.D.
1216	Report of Defendants' Expert J. Paul Waymack, M.D., Sc.D.
1217	Report of Defendants' Expert Margaret C. Fisher, M.D.

1218	Report of Defendants' Expert Steven M. Weisman, Ph.D.
1219	Curriculum Vitae of Defendants' Expert Margaret C. Fisher, M.D.
1220	Curriculum Vitae of Defendants' Expert M. Laurentius Marais, Ph.D.
1221	Curriculum Vitae of Defendants' Expert Maja Mockenhaupt, M.D., Ph.D.
1222	Curriculum Vitae of Defendants' Expert Louis A. Morris, Ph.D.
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1233	All documents disclosed and relied upon by Defendants' Expert Margaret C. Fisher, M.D.
1234	All documents disclosed and relied upon by Defendants' Expert Steven M. Weisman, Ph.D.
1235	McNeil's Briefing Materials for June 29-30, 2009, Acetaminophen Advisory Committee Meeting, titled "Section 6 Acetaminophen Use and Dosing Instructions in Children <2 Years of Age," Vol.1, pg. 141-158
1236	McNeil's Citizen's Petition dated February 1, 1999
1237	Transcript of Sept 19, 2002 Meeting of the Nonprescription Drugs Advisory Committee
1238	Facsimile from McNeil (Paula Oliver, Senior Director of Medical and Regulatory Science at McNeil) to FDA (Walter Ellenberg, Ph.D., Regulatory Project Manager for FDA), titled "Revised Warning Language," dated Oct 15, 2002
1239	Facsimile from McNeil (Paula Oliver, Senior Director of Medical and Regulatory Science at McNeil) to FDA (Walter Ellenberg, Ph.D., Regulatory Project Manager for FDA), titled "Revised Warning Language," dated Oct 16, 2002
1240	Letter from McNeil (Paula Oliver, Senior Director of Medical and Regulatory Science at McNeil) to FDA (Charles Ganley, MD, Director, Division of OTC Drug Products (HFD-560), Center for Drug Evaluation and Research at FDA), titled "Correspondence to NDA 19-872, Acetaminophen Extended Release Geltab, 650mg," dated Nov 26, 2002
1241	Letter from McNeil (Paula Oliver, Senior Director of Medical and Regulatory Science at McNeil) to FDA (Charles Ganley, MD, Director, Division of OTC Drug Products (HFD-560), Center for Drug Evaluation and Research at FDA), titled "Tylenol 8 Hour Acetaminophen Extended Release Geltab and Caplet, 650 mg, NDA 19-B72, Amendment to SNDA S014," dated May 22, 2003
1242	71 Fed. Reg. 77314 at 77315 (Dec. 26, 2006)
1243	21 U.S.C. § 355 (2010)
1244	37 Fed. Reg. 14633 (Jul. 21, 1972)
1245	42 Fed. Reg. 35346 (Jul. 8, 1977)
1246	71 Fed. Reg. 77314 (Dec. 26, 2006)
1247	74 Fed. Reg. 19385 (April 29, 2009)
1248	21 C.F.R. § 201.326 (2010)
1249	All pleadings and documents filed in case
1250	All exhibits to all depositions in this case
1251	All documents produced by Plaintiffs in discovery
1252	PDR/Labeling Aleve (May 1996)
1253	PDR/Labeling Augmentin (1993, 1994, 1995, 1996, 1998, 2000, 2002)

1254	PDR/Labeling Tylenol (1995, May 1996, 1996, 2003, 2005, 2006)
1255	PDR/Labeling Children's Motrin 1995
1256	PDR/Labeling Children's Motrin 1996
1257	PDR/Labeling Children's Motrin 1997
1258	PDR/Labeling Children's Motrin 1998
1259	PDR/Labeling Children's Motrin 1999
1260	PDR/Labeling Children's Motrin 2000
1261	PDR/Labeling Pediaprofen 1989
1262	PDR/Labeling Pediaprofen 1990
1263	PDR/Labeling Pediaprofen 1991
1264	PDR/Labeling Pediaprofen 1992
1265	PDR/Labeling Pediaprofen 1993
1266	PDR/Labeling Pediaprofen/RX Children's Motrin 1994
1267	PDR/Labeling Pediaprofen/RX Children's Motrin 1995
1268	PDR/Labeling RX Children's Motrin 1996
1269	PDR/Labeling RX Motrin 1986
1270	PDR/Labeling RX Motrin 1994
1271	PDR/Labeling RX Motrin 1995
1272	PDR/Labeling RX Motrin 1996
2001	NDA 17-463: Motrin Tablet Rx (approved 9/19/74)
2002	NDA 17-463, Motrin, Supplement to Allow OTC Marketing, August 31, 1987 Vol. 2 of 2
2003	NDA 17-463, Periodic Report (7/20/1990-6/30/1991)
2004	NDA 17-463, 9/23/1998 ADE Report
2005	NDA 17-463 Annual Report, 11/17/99
2006	NDA 17-463, Adverse Drug Experience Report, 11/18/98
2007	NDA 17-463, ADE Report (Sept. 98 - Dec. 99)
2008	NDA 17-463 Annual Report, 11/22/00
2009	Medical Officer Review, NDA 17-463
2010	NDA 17-463 Bi-Annual Report - (8/75 - 3/76) 3/12/76 [vol. 1 of 4]
2011	NDA 17-463 Bi-Annual Report - (8/75 - 3/76) 3/12/76 [vol. 2 of 4]
2012	NDA 17-463 Bi-Annual Report - (8/75- 3/76) 3/12/76 [vol. 3 of 4]
2013	NDA 17-463 Bi-Annual Report - (8/75 - 3/76)3/12/76 [vol. 4 of 4]
2014	NDA 17-463 Bi-Annual Report - (3/75 - 9/76) 9/10/76 [vol. 1 of 2]
2015	NDA 17-463 Bi-Annual Report - (3/75 - 9/76) 9/10/76 [vol. 2 of 2]
2016	NDA 17-463 Progress Report / Addendum - (9/76 - 7/77) 7/25/77 [vol. 1 of 6]
2017	NDA 17-463 Progress Report - (9/76 - 7/77) 7/25/77 [vol. 2 of 6]
2018	NDA 17-463 Progress Report - (9/76 - 7/77) 7/25/77 [vol. 3 of 6]
2019	NDA 17-463 Progress Report - (9/76 - 7/77) 7/25/77 [vol. 4 of 6]
2020	NDA 17-463 Progress Report - (9/76 - 7/77) 7/25/77 [vol. 5 of 6]
2021	NDA 17-463 Progress Report - (9/76 - 7/77) 7/25/77 [vol. 6 of 6]
2022	NDA 17-463 Progress Report - (7/77 - 7/78) 7/25/78 [vol. 1 of 8]
2023	NDA 17-463 Progress Report - (7/77 - 7/78) 7/25/78 [vol. 2 of 8]
2024	NDA 17-463 Progress Report - (7/77 - 7/78) 7/25/78 [vol. 3 of 8]
2025	NDA 17-463 Progress Report - (7/77 - 7/78) 7/25/78 [vol. 4 of 8]
2026	NDA 17-463 Progress Report - (7/77 - 7/78) 7/25/78 [vol. 5 of 8]
2027	NDA 17-463 Progress Report - (7/77 - 7/78) 7/25/78 [vol. 6 of 8]
2028	NDA 17-463 Progress Report - (7/77 - 7/78) 7/25/78 [vol. 7 of 8]
2029	NDA 17-463 Progress Report - (7/77 - 7/78) 7/25/78 [vol. 8 of 8]

2030	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 1 of 12]
2031	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 2 of 12]
2032	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 3 of 12]
2033	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 4 of 12]
2034	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 5 of 12]
2035	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 6 of 12]
2036	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 7 of 12]
2037	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 8 of 12]
2038	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 9 of 12]
2039	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 10 of 12]
2040	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 11 of 12]
2041	NDA 17-463 Progress Report - (6/78 - 5/79) 8/20/79 [vol. 12 of 12]
2042	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 1 of 15]
2043	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 2 of 15]
2044	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 3 of 15]
2045	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 4 of 15]
2046	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 5 of 15]
2047	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 6 of 15]
2048	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 7 of 15]
2049	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 8 of 15]
2050	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 9 of 15]
2051	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 10 of 15]
2052	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 11 of 15]
2053	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 12 of 15]
2054	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 13 of 15]
2055	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 14 of 15]
2056	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/80 [vol. 15 of 15]
2057	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 1 of 15]
2058	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 2 of 15]
2059	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 3 of 15]
2060	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 4 of 15]
2061	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 5 of 15]
2062	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 6 of 15]
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2064	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 8 of 15]
2065	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 9 of 15]
2066	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 10 of 15]
2067	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 11 of 15]
2068	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 12 of 15]
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2071	NDA 17-463 Progress Report - (5/79 - 5/80) 9/30/81 [vol. 15 of 15]
2072	NDA 17-463 Progress Report - (6/81 -6/82) 10/25/82 [vol. 1 of 13]
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2077	NDA 17-463 Progress Report - (6/81 -6/82) 10/25/82 [vol. 6 of 13]

2078	NDA 17-463 Progress Report - (6/81 -6/82) 10/25/82 [vol. 7 of 13]
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2084	NDA 17-463 Progress Report - (6/81 -6/82) 10/25/82 [vol. 13 of 13]
2085	NDA 17-463 1983 Progress Report - (6/82 - 6/83) 11/30/83 [vol. 1 of 9]
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2094	NDA 17-463 1984 Progress Report - (7/83 - 7/84) 10/31/84 [vol. 1 of 7]
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2126	NDA 17-463 Annual Report - (7/93 - 6/94) 11/10/94
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2134	NDA 17-463 Annual Report - (9/19/04 - 9/18/05)
2135	NDA 17-463 Annual Reports
2136	September 19, 1974 letter from FDA, re: approval of prescription adult ibuprofen
2137	December 10, 1997 letter from Pharmacia & Upjohn to FDA re ownership of the NDAs for adult Rx Motrin and OTC Motrin IB transferred to McNeil
2138	NDA 19-012: Motrin IB/ Migraine Pain OTC (approved 5/18/84)
2139	Nuprin, 1984 Progress Report (2nd Quarterly 8/84-11/84) (Upjohn), submitted 11/19/1984
2140	Medical Officer Review, NDA 19-012
2141	NDA 19-012 Progress Report (1st Quarterly)- (5/84 - 8/84) 8/17/84 [vol. 1 of 3]
2142	NDA 19-012 Progress Report (1st Quarterly)- (5/84 - 8/84) 8/17/84 [vol. 2 of 3]
2143	NDA 19-012 Progress Report (1st Quarterly)- (5/84 - 8/84) 8/17/84 [vol. 3 of 3]
2144	NDA 19-012 Progress Report (2nd Quarterly)- (8/84 - 11/84) 11/19/84
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2152	NDA 19-012 Progress Report (2nd Biannual) - 7/15/86
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2157	NDA 19-012 1990 Annual Report - (3/88 - 3/90) 5/31/90
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2160	NDA 19-012 1993 Annual Report - (4/92 - 3/93)
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2165	NDA 19-012 Annual Report - (3/1/97 - 5/18/98) 7/17/98
2166	NDA 19-012 Annual Report - (5/18/98 - 5/18/99) 11/4/99
2167	NDA 19-012 Annual Report - (5/18/99 - 5/18/00) 8/7/00
2168	NDA 19-012 Annual Report - (5/18/00 - 5/18/01) (Vol. 1) 7/20/2001
2169	NDA 19-012 Annual Report - (5/18/00 - 5/18/01) (Vol. 2) 7/20/2001
2170	NDA 19-012 Annual Report - (5/18/01 - 5/18/02) (Vol. 1) 7/19/2002
2171	NDA 19-012 Annual Report - (5/18/01 - 5/18/02) (Vol. 2) 7/19/2002
2172	NDA 19-012 Annual Report - (5/18/02 - 5/18/03) (Vol. 1)

2173	NDA 19-012 Annual Report - (5/18/02 - 5/18/03) (Vol. 2)
2174	NDA 19-012 Annual Report - (5/18/04 - 2/17/05) (Vol. 1)
2175	NDA 19-012 Annual Report - (5/18/04 - 2/17/05) (Vol. 2)
2176	NDA 19-012 Annual Report - (5/18/04 - 2/17/05) (Vol. 3)
2177	NDA 19-012 Annual Report - (2/18/05 - 2/17/06)
2178	NDA 19-012 Annual Report - (2/18/05 - 2/17/06) Addendum
2179	NDA 19-012 Annual Reports
2180	May 18, 1984 letter from FDA (Robert Temple) to The Upjohn Manufacturing Company, re: approval of NDA 19-012 for OTC Motrin Ibuprofen Tablets
2181	August 18 and 19, 1983 - Minutes of FDA's Arthritis Advisory Committee meeting to discuss NDAs 19-012 and 18-989.
2182	July 13, 1984 - NDA 19-012 and 18-989 Medical Officer Review
2183	February 25, 2000 letter from FDA (Charles Ganley and Russell Katz) to McNeil (Vivian Chester), re: approval of SNDA for Motrin Migraine Pain
2184	August 25, 2000 letter from FDA (Linda M. Katz) to McNeil (Janet A. Uetz), re: approving CBE SNDA for Motrin IB Tablets that implemented FDA-required labeling re allergy alerts and an alcohol warning
2185	October 28, 2003 from FDA to McNeil , re: NDA 19-012/S-034 (approving labeling for co-packaging)
2186	June 19, 1998 letter from McNeil (Willie D. Pagsuyuin) to FDA (Debra L. Bowen), re: MOTRIN IB Tablets and Caplets, NDA 19-012, Special Supplement - Changes Being Effected
2187	March 15, 1999 letter from McNeil (Willie D. Pagsuyuin) to FDA (Debra L. Bowen), re: Motrin IB Tablets and Caplets, NDA 19-012, Special Supplement - Changes Being Effected
2188	IND 27, 731 Supplement No. 1 3/7/86
2189	IND 27, 731 Supplement No. 2
2190	IND 27,731 Supplement No. 3 12/29/86
2191	IND 27,731 Supplement No. 4 12/29/86
2192	IND 27,731 Supplement No. 5 JAN 29, 1987
2193	IND 27,731 Supplement No. 6 JAN 29, 1987
2194	IND 27,731 Supplement No. 7 FEB 6, 1987
2195	IND 27,731 Supplement No. 8 FEB 6, 1987
2196	IND 27,731 Supplement No. 9 FEB 25, 1987
2197	IND 27,731 Supplement No. 13 MAR 20, 1987
2198	IND 27,731 Supplement No. 14 APR 28, 1987
2199	IND 27,731 Supplement No. 15 APR 28, 1987
2200	IND 27,731 Supplement No. 16 MAY 11, 1987
2201	IND 27,731 Progress Report No. 1 APR 2, 1987
2202	NDA 19-842: Motrin Suspension Rx (approved 9/19/89)
2203	NDA 19-842, OTC Switch Application Vol. 5 of 64, 12/22/1993
2204	AER on second article with same patient NDA 19-842 15-Day ADE Alert Reports,1995
2205	NDA 19-842 and 20-516 ADE Report, 8/15/2000
2206	NDA 19-842 and 20-516 Adverse Drug Experience Report, 8/12/2004
2207	NDA 19-842 Adverse Drug Experience Report, 15 Day Alert ADE Reports
2208	Medical Officer Review, NDA 19-842
2209	NDA 19-842 Annual Report No.1
2210	NDA 19-842 Annual Report No. 2
2211	NDA 19-842 Addendum to Annual Report No. 2
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2216	NDA 19-842 Annual Report No. 6
2217	NDA 19-842 Annual Report No. 7 - (9/19/95 - 9/19/96)
2218	NDA 19-842 Annual Report No. 8 - (9/19/96 - 9/19/97)
2219	NDA 19-842 Annual Report No. 9 - (9/19/97 - 9/19/98)
2220	NDA 19-842 Annual Report No. 10 - (9/19/98 - 9/19/99)
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2223	NDA 19-842 Annual Report No. 13 - (9/19/01 - 9/19/02)
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2226	NDA 19-842 Annual Report No. 17 - (3/19/05 - 3/18/06)
2227	Ibuprofen Pediatric Suspension Draft Summary Basis of Approval (6/17/89)
2228	NDA 19-842 Annual Reports
2229	September 19, 1989 letter from FDA, re: approval of prescription Pediaprofen
2230	March 21, 1989 - Letter from McNeil to FDA re: NDA 19-842 - Pediaprofen (submitting revised draft labeling for prescription ibuprofen suspension)
2231	May 3, 1990 - Letter from McNeil to FDA re: conducting study for postmarketing surveillance of Pediaprofen ibuprofen suspension
2232	February 26, 1993, Letter from McNeil to FDA re: NDA 19-824/S-004 (New Indication for Pain Relief in Patients 6 months or Older)
2233	December 3, 1993 letter from McNeil (Vivian Chester) to FDA (Linda Katz), re: NDA 19-842 (correspondence re the proposed OTC switch application)
2234	October 28, 1993 letter from McNeil (Vivian Chester) to FDA (John Harter), re: NDA 19-842 (concerning the upcoming meeting to discuss the OTC switch of Children's Motrin)
2235	November 8, 1994 - Letter from McNeil to FDA re: NDA 19-842 (follow up to November 3 meeting with FDA and submitting revised package insert)
2236	January 9, 1995 - Letter from McNeil to FDA re: NDA 19-842/S-004 (submitting SNDA providing for a new indication for relief of mild to moderate pain in patients age 6 months or older)
2237	NDA 19-842 Annual Report No. 15, September 2003- September 2004 – Part 1
2238	NDA 19-842 Annual Report No. 15, September 2003- September 2004 – Part 2
2239	NDA 20-135: Motrin Tablets (discontinued) (approved 11/16/94)
2240	Medical Officer Review, NDA 20-135
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2242	NDA 20-135 Annual Report No. 2 - (11/16/95 - 11/16/96) 3/21/97 [vol. 1 of 2]
2243	NDA 20-135 Annual Report No. 2 - (11/16/95 - 11/16/96) 3/21/97 [vol. 2 of 2]
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2245	NDA 20-135 Annual Report No. 4 - (11/16/97 - 11/16/98) 1/22/99
2246	NDA 20-135 Annual Report No. 5 - (11/16/98 - 11/16/99) 1/19/00
2247	NDA 20-135 Annual Reports
2248	NDA 20-418: Motrin Tablets (discontinued) (approved 11/16/94)
2249	NDA 20-418, Vol. 1 of 7 Ibuprofen Pediatric Caplets, 11/15/1993
2250	NDA 20-418, Vol. 2 of 7, 11/15/1993
2251	Medical Officer Review, NDA 20-418
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2253	NDA 20-418 Annual Report No. 2 - (11/16/95 - 11/16/96) 3/21/97

2254	NDA 20-418 Annual Report No. 3 - (11/16/96 - 11/16/97) 1/20/98
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2257	NDA 20-418 Annual Report No. 6 - (11/16/99 - 11/16/00) 1/22/01
2258	NDA 20-418 Annual Report No. 7 - (11/16/00 - 11/16/01) 1/4/02
2259	NDA 20-418 Annual Reports
2260	NDA 20-476: Motrin Suspension/ Drops (discontinued) (approved 5/25/95)
2261	Medical Officer Review, NDA 20-476
2262	NDA 20-476 Annual Report No. 1 - (5/25/95 - 5/25/96) 8/16/96
2263	NDA 20-476 Annual Report No. 2 - (5/25/96 - 5/25/97) 10/31/97
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2265	NDA 20-476 Annual Report No. 4 - (5/25/98 - 5/25/99) 10/19/99
2266	NDA 20-476 Annual Report No. 5 (5/25/99 - 5/25/00) 7/11/00
2267	NDA 20-476 Annual Report No. 6 (5/25/00 - 5/25/01) 6/26/2001
2268	NDA 20-476 Annual Report No. 7 (5/25/01 through 5/25/02) 7/16/2002
2269	NDA 20-476 Annual Reports
2270	NDA 20-516: Children's Motrin Suspension (approved 6/16/95)
2271	Medical Officer Review, NDA 20-516
2272	NDA 20-516 Annual Report No. 1 - (6/16/95 - 6/16/96) 2/13/97
2273	NDA 20-516 Annual Report No. 2 - 9/25/97
2274	NDA 20-516 Annual Report No. 3 - (6/16/97 - 6/16/98) 8/27/98
2275	NDA 20-516 Annual Report No. 4 - 10/27/99
2276	NDA 20-516 Annual Report No. 5 (6/16/99 - 6/16/00) 9/1/00
2277	NDA 20-516 Annual Report No. 6 (6/16/00 - 6/16/01) (Vol 1) 9/26/2001
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2279	NDA 20-516 Annual Report No. 7 (6/16/01 - 6/16/01/02) AUG 20 2002
2280	NDA 20-516 Annual Report No. 8 (6/16/02 - 6/16/03)
2281	NDA 20-516 Annual Report No. 9 (6/16/03 - 6/15/04) (Vol 1)
2282	NDA 20-516 Annual Report No. 9 (6/16/03 - 6/15/04) (Vol 2)
2283	NDA 20-516 Annual Report No. 10 (6/16/04 - 6/15/05) (Vol 1)
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2285	NDA 20-516 Annual Report No. 11: 3/16/005 - 3/15/06
2286	NDA 20-516 Annual Reports
2287	June 16, 1995 letter from FDA (Pilot Review Team) to McNeil (Vivian A. Chester), re: approval of NDA 20-516
2288	March 30, 1995 - McNeil Record of Contact with FDA (by Willie Pagsuyuin) re: NDA 20-516 (expected date of submission of revised labeling for switch application based on Advisory Committee Meeting)
2289	May 4, 1995 - Facsimile from FDA to McNeil re: Original OTC Switch Application (NDA 19-842/S-006; later NDA 20-516) (draft comments to proposed labeling for Children's Motrin ibuprofen suspension submitted April 12, 1995)
2290	May 10, 1995 - Letter from McNeil to FDA re: Original OTC Switch Application (NDA 19-842/S-006; later NDA 20-516) (response to FDA labeling comments dated May 4, 1995)
2291	May 31, 1995 - Facsimile from McNeil to FDA re: Original OTC Switch Application (NDA 19-842/S-006; later NDA 20-516) (submitting revised proposed carton and bottle labeling and package insert for Children's Motrin ibuprofen suspension)

2292	June 2, 1995 - Letter from McNeil to FDA re: Original OTC Switch Application (NDA 19-842/S-006; later NDA 20-516) (forwarding hard copy of proposed labeling reflecting FDA comments at May 24, 1995 meeting
2293	June 16, 1995 - McNeil Record of Contact with FDA (by Vivian Chester) re: confirmation that NDA 20-516 (Children's Motrin Suspension OTC) can be marketed without a package insert
2294	June 22, 1995 - Letter from McNeil to FDA re: NDA 20-516 (confirming product is approved for marketing without a package insert)
2295	October 2, 2000 letter from FDA (Linda M. Katz) to McNeil (Janet A. Uetz), re: approval of labeling for Children's Motrin in Drug Facts format
2296	Children's Motrin label, dated October 2, 2000
2297	July 27, 1995, Children's Motrin Suspension, 100mg/5mL, NDA 20-516, Final Printed Labeling
2298	July 11, 1996 - Letter from McNeil to FDA re: NDA 20-516/S-001 Submission of revised proposed labeling for Children's Motrin ibuprofen suspension re: Tamper Evident Statement and Use of Other Pain/Fever Relievers
2299	March 31, 1997 - Letter from FDA to McNeil re: NDA 20-516/S-001 (Labeling Change - Tamper Evident Statement and Use of Other Pain/Fever Relievers) (approving proposed labeling)
2300	June 20, 1997 Children's Motrin Suspension, 100 mg/5mL, NDA 20-516, S-002 (approval of tamper-evident statement and revised warning statement, and Final Printed Labeling)
2301	June 1, 1998 - Letter from McNeil to FDA re: NDA 20-516/S-004 (submitting proposed labeling changes re: Aspirin sensitive and allergy warnings)
2302	June 2, 1998 - Letter from FDA to McNeil re: NDA 20-516/S-003 (requesting additional information concerning SNDA to add 3 additional flavors of Children's Motrin ibuprofen suspension)
2303	June 3, 1998 - Letter from McNeil to FDA re: NDA 20-516/S-003 (Label Change re: 3 additional flavors) (informing FDA that application will be amended in accordance with 21 CFR 314.10)
2304	June 19, 1998 - Letter from McNeil to FDA re: NDA 20-516/S-003 (Labeling Change – 3 Additional Flavors) (submitting amendment #3 in response to FDA's June 2, 1998 request for additional information)
2305	October 23, 1998 - Letter from McNeil to FDA re: all OTC NDAs (responding to FDA suggested changes to Allergy/Aspirin-Sensitive Alert)
2306	December 2, 1998 - Letter from FDA to McNeil re: NDA 20-516/S-003 (Labeling Change – 3 Additional Flavors) (response to labeling change proposed by McNeil in June 19, 1998 amendment)
2307	December 18, 1998 - Letter from FDA to McNeil re: NDA 20-516/S-003 (Labeling Change – 3 Additional Flavors) (approving supplemental new drug application)
2308	January 21, 1999, Children's Motrin Suspension, NDA 20-516, S-003 (approval of new flavorings and Final Printed Labeling)
2309	February 11, 1999 - Facsimile from FDA to McNeil re: NDA 20-516/S-004 (providing comments and revisions to proposed labeling)
2310	August 2, 2000 - Letter from McNeil to FDA re: NDA 20-516/S-006 (Labeling Change – Changes To Conform To “Drug Facts” Content And Formatting As Set Forth In 21 CFR 201.66) (providing updated labeling pursuant to FDA comments)
2311	February 28, 2001 - Letter from FDA to McNeil re: NDA 20-516/S-003 & S-004 (acknowledging receipt of final printed labeling and requesting revised labeling)
2312	December 19, 2003 letter from FDA (Curtis Rosebraugh) to McNeil (Paula Oliver), re: NDA 20-516/S-012 and NDA 20-128/S-003 [approving new dosing instruction]
2313	February 7, 2005 letter from FDA to McNeil , re: NDA 20-516/S-016 (approving new flavors, manufacturing formulation, and labeling changes)
2314	December 7, 2005 letter from FDA to McNeil , re: NDA 20-516/S-018 (approving requested revisions to label)

2315	June 22, 2006 letter from FDA to McNeil, re: NDA 20-516/S-020 (approving four new flavors)
2316	October 28, 2003 from FDA to McNeil , re: NDA 20-516/S-012 (approving labeling for co-packaging)
2317	September 13, 1999 from FDA (Katz) to McNeil (Uetz), re: revised labeling of Children's Motrin
2318	June 4, 1998 letter from FDA (Bowen) to McNeil (Vivian A. Chester), re: approval of revised allergy warning
2319	December 20, 1990 BUFS Protocol, An Assessment of the Safety of Pediatric Ibuprofen, sponsored by McNeil Consumer Products Company
2320	McNeil Consumer Products Company Clinical Study Report Protocol 90-056, Phase IV: An Assessment of the Safety of Pediatric Ibuprofen ("Boston University Fever Study"), start date: February 2, 1991, end date: June 12, 1993; Report Date December 22, 1993
2321	BUFS Study Data in Electronic Form
2322	December 22, 1993 Children's Motrin Ibuprofen Suspension NDA 19-842 Supplemental New Drug Application (OTC Switch Application) Vols. 1-64
2323	December 22, 1993 Children's Motrin Ibuprofen Suspension NDA 19-842 Supplemental New Drug Application (OTC Switch Application) Vol. 1 of 64
2324	December 22, 1993 Children's Motrin Ibuprofen Suspension NDA 19-842 Supplemental New Drug Application (OTC Switch Application) Vol. 2 of 64
2325	December 22, 1993 Children's Motrin Ibuprofen Suspension NDA 19-842 Supplemental New Drug Application (OTC Switch Application) Vol. 3 of 64
2326	December 22, 1993 Children's Motrin Ibuprofen Suspension NDA 19-842 Supplemental New Drug Application (OTC Switch Application) Vol. 11 of 64
2327	Copies of Presentation Slides for Joint Arthritis and Nonprescription Drugs Advisory Committee Meeting, March 28, 1995
2328	March 28, 1995 Background Materials for Joint Arthritis and Nonprescription Drugs Advisory Committee Meeting, March 28, 1995 Vol. 1 of 4
2329	March 2, 1995 letter from McNeil (Vivian Chester) to FDA (Robert Bedford), re: Children's Motrin Suspension, NDA 20-516, providing FDA with a pre-meeting package re: an upcoming meeting on the Rx to OTC switch for Children's Motrin
2330	March 28, 1995 Background Materials for Joint Arthritis and Nonprescription Drugs Advisory Committee Meeting, March 28, 1995 Vol. 2 of 4
2331	March 28, 1995 Background Materials for Joint Arthritis and Nonprescription Drugs Advisory Committee Meeting, March 28, 1995 Vol. 3 of 4
2332	March 28, 1995 Background Materials for Joint Arthritis and Nonprescription Drugs Advisory Committee Meeting, March 28, 1995 Vol. 4 of 4
2333	January 27, 1995 letter and submissions from McNeil (Vivian A. Chester) to FDA (Rudolph L. Widmark), re: Children's MOTRIN (ibuprofen) Suspension, 100 mg/5 mL, Draft Pre-Meeting Package Infant's Motrin Concentrated Drops
2334	January 29, 1990 Minutes of Industry Meeting with FDA Post Marketing Surveillance Program - Ibuprofen Suspension
2335	June 15, 1998 letter from McNeil (Vivian A. Chester) to FDA (Debra L. Bowen), re: Submission Of Pediatric Study Reports - Pediatric Exclusivity Determination Requested
2336	October 13, 1999 letter from McNeil (Janet A. Uetz) to FDA (Charles Ganley), re: NDA 20-516, Children's MOTRIN (ibuprofen) Suspension, SNDA - Labeling In Drug Facts Format
2337	October 13, 1999, Children's Motrin Suspension, 100mg/5mL, NDA 20-516, SNDA S-006 (Drug Facts Labeling)
2338	Children's Motrin Suspension, 100mg/5mL, NDA 20-516/SNDA S-006, Drug Facts Labeling, 10/13/99

2339	October 22, 2000 letter from FDA (Maria Rossana R. Cook) to McNeil (Janet A. Uetz), re: acknowledging receipt of SNDA for labeling for Children's Motrin in Drug Facts format
2340	September 15, 1998 letters from FDA (Debra L. Bowen) to McNeil (Vivian A. Chester) and Pharmacia & Upjohn Company (Kenneth King), re: implementation of new class labeling
2341	February 11, 2002 letter from McNeil (Paula Oliver) to FDA (Charley Ganley), re: Children's Motrin Ibuprofen Suspension, NDA 20-516, Special Supplement - Changes Being Effected
2342	May 23, 2002 letter from FDA (David Hilfiker) to McNeil (Paula Oliver), re: information request letter re McNeil's proposed new overdose warning
2343	July 2, 2002 letter from McNeil (Paula Oliver) to FDA (Charles Ganley), re: Children's Motrin Suspension, NDA 20-516/S-009, Response To Information Request Letter
2344	July 20, 2002 letter from FDA (Charles Ganley) to McNeil (Paula Oliver), re: finding McNeil's CBE for a new overdose warning to be not approvable
2345	Patient Data Listing for patient 00282-21779
2346	Patient Data Listing for patient 00282-21780
2347	Enrollment Form for patient 00282-21779
2348	Enrollment Form for patient 00282-21780
2349	February 19, 1993 letter from Allen Mitchell and Samuel Lesko to Barbara Korberly re ADR reports for 1992 for the Boston University Fever Study
2350	June 20, 1997, Children's Motrin Suspension, 100mg/5mL, NDA 20-516, S-002 (Labeling)
2351	March 1997 letter from FDA (Wiley Chambers) to McNeil (Vivian Chester), re: Children's Motrin Suspension, NDA 20-516/S-001, approving revised tamper-evident statement and warning statement regarding use with other pediatric ibuprofen products
2352	June 20, 1997 letter from McNeil () to FDA (Debra Bowen), re: Children's Motrin Suspension, NDA 20-516, submitting Changes Being Effected re revised Aspirin Sensitive Warnings
2353	March 22, 1995, Motrin (ibuprofen) Suspension, 100mg/5mL, NDA 20-516, Amendment No. 2 - (Draft Labeling)
2354	Children's Motrin Suspension, 100mg/5mL, NDA 20-516, Final Printed Labeling, 7/27/95
2355	Children's Motrin Suspension, 100mg/5mL, Correspondence to NDA 20-516, 4/12/95
2356	May 26, 1993 letter and attachments from McNeil (Vivian Chester) to FDA (John Harter), re: NDA 19-842 (requesting pre-NDA meeting)
2357	July 5, 1995 letter and attachments from FDA (Rudolph Widmark) to McNeil (Vivian Chester), re: NDA 20-516 (attaching copy of June 16, 1995 approval letter)
2358	July 21, 1997 letter from FDA (Michael Weintraub) to McNeil (Vivian Chester), re: NDA 20-516 (stating the FDA is evaluating issues regarding class labeling for NSAIDs)
2359	December 22, 1993 letter from McNeil (Vivian Chester) to FDA (Linda Katz), re: NDA 19-842, S-006 (submitting information in support of SNDA S-006)
2360	December 22, 1993 facsimile from McNeil (Willie Pagsuyuin) to FDA (Sandy Barnes), re: NDA 19-842 (computer submission of SNDA)
2361	December 15, 1993 McNeil Record of Contact (by Willie Pagsuyuin), re: NDA 19-842 (computer submission of SNDA)
2362	December 7, 1993 McNeil Record of Contact (by Willie Pagsuyuin), re: FDA meeting to discuss OTC application for Children's Motrin
2363	December 8, 1993 facsimile from McNeil (Willie Pagsuyuin) to FDA (Sandy Barnes), re: NDA 19-842 (computer submission of SNDA)
2364	January 11, 1991 letter from Samuel Lesko to Anthony Temple, re: the packet of materials sent to prospective investigators for BUFS
2365	BUFS investigator packet
2366	Investigator brochure supplied to BUFS investigators

2367	Questionnaire used in BUFS
2368	June 1, 1998, Letter from McNeil to FDA re: NDA 20-516/S-004 (Clarify Aspirin Sensitive and Allergy Warnings)
2369	June 15, 1998, Letter from McNeil to FDA re: NDA 20-516/S-005 (Labeling Change - Expansion of Approved Age Group)
2370	NDA 20-601: Children's Motrin/ Jr Strength Tablets OTC (approved 11/15/96)
2371	Medical Officer Review, NDA 20-601
2372	NDA 20-601 Annual Report No. 1 – 1/16/98
2373	NDA 20-601 Annual Report No. 2 - (11/15/97 -11/15/98) 2/5/99
2374	NDA 20-601 Annual Report No. 3 – 2/2/00
2375	NDA 20-601 Annual Report No. 4 2/8/2001
2376	NDA 20-601 Annual Report No. 5 (11/15/00 - 11/15/01) 1/28/2002
2377	NDA 20-601 Annual Report No. 5 (11/15/00 - 11/15/01) Addendum 3/7/2002
2378	NDA 20-601 Annual Report No. 6 (11/15/01 - 11/15/02)
2379	NDA 20-601 Annual Report No. 7 (11/15/02 - 11/15/003)
2380	NDA 20-601 Annual Report No. 8 (11/15/03 - 11/14/04)
2381	NDA 20-601 Annual Report No. 9 (11/15/004 - 3/9/05)
2382	NDA 20-601 Annual Report No. 10 (3/10/05 - 3/9/06) Vol. 1
2383	NDA 20-601 Annual Report No. 10 (3/10/05 - 3/9/06) Vol. 2
2384	NDA 20-601 Annual Report No. 10 (3/10/05 - 3/9/06) Vol. 3
2385	NDA 20-601 Annual Report No. 10 (3/10/05 - 3/9/06) Vol. 4
2386	NDA 20-601 Annual Report No. 10 (3/10/05 - 3/9/06) Vol. 5
2387	NDA 20-601 Annual Reports
2388	November 15, 1996 letter from FDA (Wiley Chambers) to McNeil (Vivian Chester), re: NDA 20-601 (approving of OTC Children's Motrin and Jr. Strength Motrin tablets)
2389	June 18, 1998, Children's/Junior Strength Motrin Chewable Tablets, NDA 20-601, S-003 (approval of new packaging and Final Printed Labeling)
2390	August 21, 1996 - Letter from McNeil to FDA re: NDA 20-601, Amendment #12 (Children's Motrin Chewable Tablets) (response to FDA changes to Aspirin sensitive children warning)
2391	September 30, 1996 - Letter from McNeil to FDA re: NDA 20-601 (Children's Motrin Chewable Tablets) (submitting revised labeling re: dosing chart and Aspirin sensitive children warning)
2392	June 1, 1998 - Letter from McNeil to FDA re: NDA 20-601/S-002 (submitting proposed labeling changes re: Aspirin sensitive and allergy warnings)
2393	December 8, 1998 - Facsimile from FDA to McNeil re: NDA 20-601/SCP3 (SNDA for Children's/Junior Strength Motrin Chewable Tablets) (comments re: proposed labeling)
2394	December 9, 1998 - Letter from McNeil to FDA re: NDA 20-601/SCP3 (SNDA for Children's/Junior Strength Motrin Chewable Tablets) (response agreeing to institute requested labeling changes)
2395	December 29, 1999 letter from FDA (Ganley) to McNeil (Vivian A. Chester), re: approval of OTC Children's and Junior Strength Motrin (tablets) formulation change and revised labeling
2396	May 10, 2006 Approval Letter NDA 20-601/S-014
2397	February 27, 2006 letter from FDA (Andrea Leonard-Segal) to McNeil (Hina Harlow), re: NDA 20-601/S-013 (approving requested revisions to label)
2398	December 8, 2005 letter from McNeil (Hina Harlow) to FDA (Charles Ganley), re: NDA 20-601 (Supplement - Changes Being Effected)
2399	May 10, 2006 letter from FDA to McNeil , re: NDA 20-601/S-014 (approving addition of dosing directions for children 2 to 5 years of age)
2400	NDA 20-602: Junior Strength Motrin (approved 6/10/96)

2401	Medical Officer Review, NDA 20-602
2402	NDA 20-602 Annual Report No. 1 - 9/25/97
2403	NDA 20-602 Annual Report No. 2 - 8/11/98
2404	NDA 20-602 Annual Report No. 3 - (6/10/98 - 6/10/99) 10/22/99
2405	NDA 20-602 Annual Report No. 4 (6/10/99 - 6/10/00)
2406	NDA 20-602 Annual Report No. 5 (6/10/00 - 6/10/01) 8/16/2001
2407	NDA 20-602 Annual Report No. 6 (6/10/01 - 6/10/02)
2408	NDA 20-602 Addendum To Annual Report No. 6 (6/10/01 - 6/10/02)
2409	NDA 20-602 Annual Report No. 7 (6/10/02 - 6/10/03)
2410	NDA 20-602 Annual Report No. 8 (6/10/03 - 6/9/04) Vol. 1
2411	NDA 20-602 Annual Report No. 8 (6/10/03 - 6/9/04) Vol. 2
2412	NDA 20-602 Annual Report No. 9 (6/10/04 - 3/9/05)
2413	NDA 20-602 Annual Report No. 10 (3/10/05 -3/9/06)
2414	NDA 20-602 Annual Reports
2415	June 10, 1996 letter from FDA (Chambers) to McNeil (Vivian A. Chester), re: approval of OTC Junior Strength Motrin (tablets)
2416	July 21, 1997 - Letter from FDA to McNeil re: NDA 20-602 (class labeling for internal analgesic drug products related to alcohol and aspirin sensitive patients should not be implemented until completion of FDA evaluation)
2417	June 1, 1998 - Letter from McNeil to FDA re: NDA 20-602/S-003 (submitting proposed labeling changes re: Aspirin sensitive and allergy warnings)
2418	May 10, 1996, Junior Strength Motrin Tablet, 00 mg, NDA 20-602 (Final Printed Labeling)
2419	April 4, 1997, Letter from McNeil to FDA re: NDA 20-602/S-001 (Labeling Change - Consistent with Approved OTC Labeling)
2420	June 20, 1997, Letter from McNeil to FDA re: NDA 20-602/S-002 (Clarify Aspirin Sensitive and Allergy Warnings)
2421	June 1, 1998, Letter from McNeil to FDA re: NDA 20-602/S-003 (Clarify Aspirin Sensitive and Allergy Warnings)
2422	February 27, 2006 letter from FDA (Andrea Leonard-Segal) to McNeil (Hina Harlow), re: NDA 20-602/S-008 (approving requested revisions to label)
2423	November 10, 2005 letter from McNeil (Hina Wu) to FDA (Charles Ganley), re: NDA 20-602 (Supplement - Changes Being Effected)
2424	NDA 20-603: Children’s Motrin Drops OTC (approved 6/10/96)
2425	Medical Officer Review, NDA 20-603
2426	NDA 20-603 Annual Report No. 1 - 9/25/97
2427	NDA 20-603 Annual Report No. 2 - (6/10/97 - 6/10/98) 8/26/98
2428	NDA 20-603 Annual Report No. 3 - (6/10/98 - 6/10/99) 10/19/99
2429	NDA 20-603 Annual Report No. 4 (6/10/99 - 6/10/00) 8/23/00
2430	NDA 20-603 Annual Report No. 5 (6/10/00 - 6/10/01) 8/24/01
2431	NDA 20-603 Annual Report No. 6 (06/10/2001 - 06/10/2002)
2432	NDA 20-603 Annual Report No. 7 6/10/2002 - 06/10/2003)
2433	NDA 20-603 Annual Report No. 8 (6/10/2003 - 06/9/2004) Vol. 1
2434	NDA 20-603 Annual Report No. 8 (6/10/2003 - 06/9/2004) Vol. 2
2435	NDA 20-603 Annual Report No. 9 (6/10/2004 - 03/9/2005) Vol. 1
2436	NDA 20-603 Annual Report No. 9 (6/10/2004 - 03/9/2005) Vol. 2
2437	NDA 20-603 Annual Report No. 10 (3/2005 - 03/2006)
2438	NDA 20-603 Annual Reports

2439	June 10, 1996 letter from FDA (Chambers) to McNeil (Vivian A. Chester), re: approval of OTC Children's Motrin (oral suspension) in Children 2 years of age and older
2440	May 10, 1996, Children's Motrin Oral Drops, 40 mg/mL, NDA 20-603 (Final Printed Labeling)
2441	June 8, 1998 - Letter from FDA to McNeil re: NDAs 20-603 and 20-516 (official Written Request for health benefit information for pediatric population)
2442	August 4, 1998, Children's Motrin Drops, 40mg/mL, NDA 20-603, S-001 (approval of revised allergy warning and Final Printed Labeling)
2443	April 15, 1999 letter from FDA (Linda M. Katz) to McNeil (Vivian A. Chester), re: approval of the SNDA to expand use of Infant's Motrin Concentrated Drops to include children between 6 and 23 months of age
2444	January 16, 2002 letter from FDA (Ganley) to McNeil (Lynn A. Pawelski), re: approval of revised labeling for Infants' Motrin
2445	February 27, 2006 letter from FDA (Andrea Leonard-Segal) to McNeil (Hina Harlow), re: NDA 20-603/S-011 (approving requested revisions to label)
2446	December 12, 2005 letter from McNeil (Hina Harlow) to FDA (Charles Ganley), re: NDA 20-603 (Supplement - Changes Being Effected)
2447	April 8, 1999 facsimile from FDA (Kerry G. Rothschild) to McNeil (Willie D. Pagsuyuin), re: attaching FDA-revised labeling for Infant's Motrin Concentrated Drops
2448	April 8, 1999 facsimile from FDA (Kerry G. Rothschild) to McNeil (Willie D. Pagsuyuin), re: attaching FDA-revised labeling for Children's Motrin
2449	April 13, 1999 letter from McNeil (Willie D. Pagsuyuin) to FDA (Debra L. Bowen), re: Children's Motrin Drops, NDA 20-603/S-003, Response to FDA Comments
2450	April 14, 1999 letter from McNeil (Willie D. Pagsuyuin) to FDA (Debra L. Bowen), re: NDA 20-603/S-003, Children's MOTRIN Oral Drops
2451	June 15, 1998 Children's Motrin ibuprofen Drops, 50mg/1.25mL, NDA 20-603, Supplemental New Drug Application [vol. 1 of 4]
2452	June 15, 1998 Children's Motrin ibuprofen Drops, 50mg/1.25mL, NDA 20-603, Supplemental New Drug Application [vol. 2 of 4]
2453	June 15, 1998 Children's Motrin ibuprofen Drops, 50mg/1.25mL, NDA 20-603, Supplemental New Drug Application [vol. 3 of 4]
2454	June 15, 1998 Children's Motrin ibuprofen Drops, 50mg/1.25mL, NDA 20-603, Supplemental New Drug Application [vol. 4 of 4]
2455	April 15, 1999 letter from McNeil (Willie D. Pagsuyuin) to FDA (Debra L. Bowen), re: Infant's Motrin Concentrated Drops, NDA 20-603/S-003, Revised Commitment Letter
2456	April 15, 1999 facsimile from FDA (Kerry G. Rothschild) to McNeil (Willie D. Pagsuyuin), re: attaching FDA-revised labeling for Infant's Motrin Concentrated Drops
2457	March 9, 2001 letter from FDA (Linda M. Katz) to McNeil (Janet A. Uetz), re: acknowledging receipt of final printed labeling for Infant's Motrin Concentrated Drops
2458	March 4, 1998 internal FDA Labeling Review memo, re: NDA 20-603, S-001
2459	January 11, 1999 internal FDA Labeling Review memo, re: NDA 20-603, SLR-002
2460	April 15, 1999 internal FDA Labeling Review memo, re: NDA 20-603, SE5-003
2461	June 1, 1998 letter from McNeil (Vivian Chester) to FDA (Debra Bowen), re: NDA 20-603, Special Supplement - Changes Being Effected
2462	June 20, 1997 letter from McNeil (Vivian Chester) to FDA (Debra Bowen), re: NDA 20-603, Special Supplement - Changes Being Effected
2463	NDA 21-128: Children's Motrin Cold OTC (approved 8/1/00)
2464	Medical Officer Review, NDA 21-128
2465	NDA 21-128 Annual Reports

2466	August 1, 2000 letter from FDA to McNeil, re: NDA 21-128 (approving Children's Motrin Cold OTC)
2467	June 11, 1986 - Letter from McNeil to FDA re: ANDA 70-081 - Ibuprofen (matching Motrin package insert labeling)
2468	June 16, 1986 - Letter from FDA to McNeil re: ANDA 70-081 (approving generic prescription Ibuprofen tablets (400mg))
2469	September 24, 1984, ANDA 70-081, New Drug Application (Vol. 1)
2470	ANDA 70-081, Vol. 1 of 5, 9/24/84
2471	ANDA 70-081, Vol. 4 of 5, 9/24/84
2472	ANDA 70-081, Vol. 5 of 5, 9/24/84
2473	ANDA 70-081, Annual Report No. 1
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2486	ANDA 70-081, Annual Report No. 14
2487	ANDA 70-081, Annual Report No. 15
2488	ANDA 70-081, Annual Report No. 16
2489	ANDA 70-081, Annual Report No. 17
2490	ANDA 70-081, Annual Report No. 18
2491	ANDA 70-081, Annual Report No. 19
2492	ANDA 70-081, Annual Report No. 20
2493	ANDA 70-081, Annual Report No. 21
2494	ANDA 70-475: Medipren Caplet (Approved 2/6/86)
2495	February 6, 1986 - Letter from FDA to McNeil re: ANDA 70-475 (approving Medipren caplet application)
2496	ANDA 70-475, Annual Report No. 1 and Amendment
2497	ANDA 70-475, Annual Report No. 2
2498	ANDA 70-475, Annual Report No. 3
2499	ANDA 70-475, Annual Report No. 4 [vol. 1 of 3]
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2504	ANDA 70-475, Annual Report No. 5 [vol. 3 of 5]
2505	ANDA 70-475, Annual Report No. 5 [vol. 4 of 5]
2506	ANDA 70-475, Annual Report No. 5 [vol. 5 of 5]
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2508	ANDA 70-475, Annual Report No. 6 [vol. 2 of 3]
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2510	ANDA 70-475, Addendum to Annual Report No. 6
2511	ANDA 70-475, Annual Report No. 7
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2515	ANDA 70-475, Annual Report No. 11
2516	ANDA 70-475, Annual Report No. 12
2517	ANDA 70-475, Annual Report No. 13
2518	June 11, 1986 - Letter from McNeil to FDA re: ANDA 70-476 - Ibuprofen (matching Motrin package insert labeling)
2519	June 16, 1986 - Letter from FDA to McNeil re: ANDA 70-476 (approving generic prescription Ibuprofen tablets (600 mg))
2520	ANDA 71-215 Medipren Ibuprofen Round Tablets (Approved 6/26/86)
2521	June 26, 1986 - Letter from FDA to McNeil re: ANDA 71-215 (approving Medipren tablets)
2522	ANDA 71-215, Annual Report No. 1
2523	ANDA 71-215, Annual Report No. 2
2524	ANDA 71-215, Annual Report No. 3
2525	ANDA 71-215, Annual Report No. 4
2526	ANDA 71-215, Annual Report No. 5
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2530	ANDA 71-215, Annual Report No. 9
2531	ANDA 71-215, Annual Report No. 10
2532	ANDA 71-215, Annual Report No. 11
2533	ANDA 71-215, Annual Report No. 12
2534	ANDA 71-215, Annual Report No. 13
2535	December 20, 1996 letter and attachments from FDA (Wiley Chambers) to McNeil (Vivian Chester), re: NDA 19-842, 20-135, 20-476, and 20-418 (requesting revisions to labeling of all NSAID products)
2536	November 19, 1998 McNeil Record of Contact (by Willie Pagsuyuin), re: the new allergy warning for OTC ibuprofen products
2537	April 21, 2003 email (string) from Anthony Temple to Helen Hohman, re: Ovid Citations for SJS and ibuprofen or NSAIDs
2538	April 21, 2003 email (string) from Helen Hohman to Anthony Temple, re: Ovid Citations for TEN and ibuprofen or NSAIDs
2539	All NDAs for all ibuprofen products
2540	All correspondence with FDA re approval of NDAs, SNDAs and ANDAs for ibuprofen products
2541	All correspondence with FDA re approval of labeling for ibuprofen products
2542	All correspondence with FDA re approval of new indications for ibuprofen products
2543	All correspondence with FDA re approval of new formulations for ibuprofen products
2544	SOPs for Adverse Drug Experience Reporting
2545	SOPs for Literature reporting
2546	SOP 99-RD-PV-001 - Adverse Drug Experience Reporting
2547	SOP 99-RD-MA-011 - Literature Review for McNeil's Product Literature Database/FDA Reporting
2548	SOP 99-RD-MA-001 - Adverse Drug Experience Reporting
2549	SOP 99-RD-PV-002 - Procedures for Handling Safety Information for Adult, Single-ingredient, OTC ibuprofen-containing products and Rx Motrin

2550	SOP 99-RD-PV-008 - Documentation of SOP and Procedure Deviation
2551	SOP 99-RD-PV-011 - Identifying and Reporting Adverse Events (AEs) from the Medical Literature
2552	SOP 99-RD-PV-011 2.0 - Identifying and Reporting Adverse Events (AEs) from the Medical Literature
2553	SOP 99-RD-PV-012 - Obtaining Follow-up Information on Spontaneous Adverse Drug Experience(s) and Health Experience(s)
2554	SOP 99-RD-PV-013 - Determining Expectedness of Adverse Event Reports
2555	SOP 99-RD-PV-015 - Procedure for MCSP Safety Review Board Identification and Review of Safety Signals
2556	SOP 99-RD-PV-016 - Adverse Experience Monitoring Process
2557	SOP 99-RD-PV-020 - Procedure for the Exchange of Adverse Event Information Between Local Operating Companies and McNeil Consumer & Specialty Pharmaceuticals
2558	SOP 99-RD-PV-021 - Pharmacovigilance (PV) Process for Serious Adverse Experiences (SAEs) Received from Clinical Trials
2559	U.S. Ibuprofen Marketing Data (Doses sold)
2560	July 2005 letter FDA to NSAID manufacturers re: supplemental labeling changes
2561	June 14, 2005 letter FDA to NSAID manufacturers re: labeling changes
2562	June 14, 2005 letter FDA (Rosebraugh) to McNeil (Wagner-Weber) re: labeling changes
2563	July 15, 2005 letter FDA to McNeil re: supplemental labeling changes
2564	April 7, 2005, Facsimile from FDA to McNeil re: FDA Supplemental Labeling Request, NDAs 20-516, 20-601, 20-602, 20-603, 21-128, re: Feb. 16-18, 2005 Arthritis and Drug Safety and Risk Management Advisory Committees
2565	August 11, 2005, Letter from McNeil to FDA re: NDA 20-516/S-018 (Response to FDA Supplemental Label Request)
2566	July 12, 2005 - Letter from McNeil to FDA re: NDA 19-842 (response to FDA NSAID labeling request dated 6/14/05)
2567	September 15, 2005, Letter from McNeil to FDA re: NDA 19-824/S-019 (Response to Class Labeling for Non-Selective NSAIDs to Include Boxed Warnings re: CV and GI Risks)
2568	November 4, 2005 - Revised Packaging and Labeling re: FDA Supplemental Labeling Request - CBE for NDA 20-516/S-008
2569	December 20, 2005 - Letter from FDA to McNeil re: NDA 20-602/S-008
2570	Letter to Dr. Wu approving 2005 label changes
2571	March 28, 1995 Arthritis and non-prescription drug advisory committees joint meeting – minutes and/or recommendations
2572	April 7, 2005 Questions and Answers: FDA Regulatory Actions for the COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
2573	June 22, 2006 letter FDA (Galson) to Salisbury re: Response to the Citizen's Petition
2574	April 6, 2005 Memorandum, FDA (Jenkins and Seligman "through" Galson) to NDA Files 20-998, 21-156, 21-341, 21-042
2575	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 1 of 11]
2576	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 2 of 11]
2577	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 3 of 11]
2578	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 4 of 11]
2579	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 5 of 11]
2580	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 6 of 11]
2581	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 7 of 11]
2582	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 8 of 11]
2583	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 9 of 11]

2584	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 10 of 11]
2585	March 31, 1988 NDA 19-842, Ibuprofen Pediatric Suspension [vol. 11 of 11]
2586	June 6, 1995 McNeil to FDA
2587	April 12, 1995 McNeil to FDA re submission of revised labeling based on recommendations made at 3/28/95 FDA meeting
2588	PDR/label for OTC Children's Advil (1997)
2589	NDA 20-944 Children's Advil Final Printed Labeling approved 12/18/98
2590	NDA 20-944 Medical Officer's Review; dated February 24, 1998, revised July 16, 1998
2591	NDA 20-812 January 30, 1998 approval letter
2592	NDA 20-812 June 6, 1997 approvable letter
2593	NDA 20-812 Medical Officer's Review; dated January 2, 1997
2594	NDA 21-373 April 18, 2002 approval letter
2595	NDA 21-373 Medical Officer's Review; dated March 28, 2002
2596	NDA 21-587 Medical Officer's Review; dated February 12, 2004
2597	NDA 21-587 Medical Officer's Review; dated November 14, 2003
2598	NDA 21-587 February 24, 2004 approval letter
2599	NDA 21-604 Medical Officer's Review; dated December 19, 2003
2600	NDA 21-604 Medical Officer's Review; dated October 30, 2003
2601	NDA 21-604 Medical Officer's Review; dated August 12, 2003
2602	NDA 21-604 January 7, 2004 approval letter
2603	NDA 21-373 Final Printed Labeling, dated April 18, 2002
2604	NDA 21-587 Final Printed Labeling, dated February 24, 2004
2605	NDA 20-944 Children's Advil December 18, 1998 approval letter
2606	ANDA 74-937 December 22, 1998 approval letter
2607	ANDA 74-937 Approved Labeling September 5, 1997 approval letter
2608	Approved package/label for Children's Tylenol Cold
2609	May 4, 1995 fax from FDA (Susan Guckenheimer) to McNeil (Vivian Chester) re: changes to Children's Motrin labeling
2610	May 10, 1995 letter from McNeil (Vivian Chester) to FDA (Robert Bedford), re: Children's Motrin Suspension, NDA 20-516, responding to FDA's labeling changes received via fax on 5/4/95
2611	Seractil Product Labeling/Package Insert 2000-2006
2612	February 22, 1999 facsimile from FDA (Kerry G. Rothschild) to McNeil (Willie D. Pagsuyuin), re: NDA 19-012/S-15
2613	September 27, 1996 facsimile from FDA (Susan Raigrodski) to McNeil (Vivian Chester), re: NDA 20-602, NDA 20-603, NDA 20-516, NDA 20-601
2614	July 11, 1996 letter from FDA (Wiley Chambers) to McNeil (Vivian Chester), re: Children's Motrin Suspension, NDA 20-516/S-001, approving revised tamper-evident statement and warning statement regarding use with other pediatric ibuprofen products
2615	December 1, 1998 Record of Contact with FDA re NDA 20-516 and others (allergy warnings for adult and children’s OTC Motrin products)
2616	December 2, 1998 Fax Transmission Record re NDA 20-516 (change from “Aspirin Sensitive Children” to “Allergy Alert”)
3001	60 Federal Register 47752 (September 1995)
3002	68 Federal Register 18861 (April 2003)
3003	63 Federal Register 63378
3004	21 CFR 201.323 (2008) - special regs re: parenteral nutrition
3005	21 CFR 201.325 (2008) - special regs re: analgesics/alcohol warning
3006	21 CFR 201.322 (2008) - special regs re: analgesics/alcohol warning

3007	21 CFR 201.320 (2008) - special regs re: ozone depleting substances
3008	21 CFR 201.317 (2008) - special regs re: digitalis
3009	21 CFR 201.319 (2008) - special regs re: gums
3010	21 CFR 201.315 (2008) - special regs re: OTC for sore throats
3011	21 CFR 201.316 (2008) - special regs re: thyroid hormone therapy
3012	21 CFR 201.314 (2008) - special regs re: salicyclates
3013	21 CFR 201.312 (2008) - special regs re: magnesium sulfate
3014	21 CFR 201.313 (2008) - special regs re: estradiol
3015	21 CFR 201.308 (2008) - special regs re: ipecac syrup
3016	21 CFR 201.310 (2008) - special regs re: phenendione
3017	21 CFR 201.309 (2008) - special regs re: acetophenetidin
3018	21 CFR 201.307 (2008) - special regs re: sodium sulfates
3019	21 CFR 201.306 (2008) - special regs re: potassium salt preparations
3020	21 CFR 201.305 (2008) - special regs re: nebulizers
3021	21 CFR 201.304 (2008) - special regs re: enema preparations
3022	21 CFR 201.303 (2008) - special regs re: wintergreen oil
3023	21 CFR 201.302 (2008) - special regs re: mineral oil
3024	21 CFR 201.301 (2008) - special regs re: estrogen therapy
3025	21 CFR 201.300 (2008) - special regs re: glandular prods
3026	44 U.S.C. 1507
3027	21 U.S.C. 379r
3028	37 Federal Register 16503 - 1972 Federal Register Rx label rule (August 15, 1972)
3029	37 Federal Register 85 (January 5, 1972)
3030	37 Federal Register 9464 (May 11, 1972)
3031	37 Federal Register 10358 (May 20, 1972)
3032	38 Federal Register 31258 (November 12, 1973)
3033	40 Federal Register 11717 (March 13, 1975)
3034	39 CFR 11680 Recodification (March 1974)
3035	39 Federal Register 11741 - labeling of OTC and other drugs (March 1974)
3036	39 Federal Register 11745 - warnings for OT Drugs (March 1974)
3037	40 Federal Register 8917 - warnings on pharmaceutical aerosol products (March 1975)
3038	40 Federal Register 11718 - OTC labeling as to keep out of children's reach (March 1975)
3039	40 Federal Register 13996 - recodification of 21 CFR (March 27, 1975)
3040	41 Federal Register 6896 - labeling and packaging for medical devices (February 1976)
3041	41 Federal Register 10885 - revising CFR to reflect changes in cross-references to other sections (March 1976)
3042	42 Federal Register 15673, 15674 (March 1977)
3043	42 Federal Register 22033 - amends 21 CFR 369 re warnings for propellants (April 1977)
3044	42 Federal Register 36994 - prescription for med for athlete's feet (July 1977)
3045	43 Federal Register 45077, 45087 - amendments to 21 CFR Part 211 (September 1978)
3046	44 Federal Register 22053 (April 1979)
3047	44 Federal Register 55170 - amendment re insulin to (September 1979)
3048	46 Federal Register 8454 - OTC labeling for safety of children (January 1981)
3049	47 Federal Register 46622, 46623 (October 19, 1982)
3050	47 Federal Register 54750 (December 3, 1982)
3051	47 Federal Register 50442 - OTC re tamper resistant packaging (November 1982)
3052	47 Federal Register 57886 - advance notice of proposed rule for aspirin label change (December 1982)

3053	48 Federal Register 16658, 16664 - tamper-resistant packaging (April 1983)
3054	48 Federal Register 32396 - Notice of 8-18-83 Meeting of Arthritis Advisory Committee
3055	48 Federal Register 37624 (August 1983)
3056	48 Federal Register 46979 (October 1988)
3057	50 Federal Register 51400 - proposed rule for aspirin label change (December 1985)
3058	51 Federal Register 8180 - final rule on aspirin label change (March 1986)
3059	51 Federal Register 16258 - labeling of drug products (April 1986)
3060	51 Federal Register 27756, 27759 amend 21 CFR 368 re: anthelmintic drugs Aug. 1986
3061	51 Federal Register 31763 (September 1986)
3062	51 Federal Register 35326, 35340 - ephedrine (October 1986)
3063	52 Federal Register 15886, 15893 - cyclizine (April 1987)
3064	52 Federal Register 47312, 47324 - topical antibiotics (November 1987)
3065	53 Federal Register 46204 (November 16, 1988)
3066	53 Federal Register 7076, 7096 - ophthalmic drugs (March 1988)
3067	54 Federal Register 39630, 39636 (September 1989)
3068	55 Federal Register 11575, 11582 - dispensors with propellants (March 1990)
3069	55 Federal Register 31776 (August 1990)
3070	57 Federal Register 58356, 58376 (December 1992)
3071	59 Federal Register 3998 (January 28, 1994)
3072	59 Federal Register 4216, 4218 (January 1994)
3073	59 Federal Register 43386, 43412 (August 1994)
3074	60 Federal Register 42578 - re OTC labels
3075	60 Federal Register 44182 - 1995 proposed reg re: patient information (1995)
3076	60 Federal Register 52474, 52510 (October 1995)
3077	61 Federal Register 8450 - March 1996 Proposed OTC rules
3078	61 Federal Register 20096, 20101 (May 1996)
3079	62 Federal Register 9024 (February 27, 1997)
3080	62 Federal Register 51512, 51517 (October 1997)
3081	Guidance for Industry – National Uniformity for Nonprescription Drugs - Ingredient Listing for OTC Drugs (April 1998)
3082	63 Federal Register 26694, 26698 - re: insulin (May 1998)
3083	63 Federal Register 48576 - re: insulin change (September 1998)
3084	64 Federal Register 396, 403 (January 1999)
3085	64 Federal Register 13,254 (March 17, 1999)
3086	64 Federal Register 18571 (April 1999)
3087	64 Federal Register 67291 (December 1, 1999)
3088	65 Federal Register 7, 8 - re: warnings (January 2000)
3089	65 Federal Register 38191 - change in compliance date (June 2000)
3090	65 Federal Register 79371 (December 19, 2000)
3091	2002 Federal Register proposed rule change re: OTC anti-inflammatories
3092	67 Federal Register 54139 (August 21, 2002)
3093	68 Federal Register 18869, 18882 - re: diarrhea medicines (April 2003)
3094	68 Federal Register 32273, 34293 - re: antiperspirants (June 2003)
3095	2006 Federal Register proposed rule change on OTC NSAIDs
3096	71 Federal Register 3922, 3934 (January 24, 2006)
3097	72 Federal Register 67639 - cough & cold (November 2007)
3098	Fed Reg CBE 2008
3099	73 Federal Register at 284850 (January 16, 2008)

3100	21 CFR 314.70
3101	21 CFR 314.80
3102	21 CFR 341 (2008)
3103	21 CFR 201.66 et seq.
3104	21 CFR 201.57 (1995)
3105	21 CFR 312.32
3106	21 CFR 312.64
3107	21 CFR 314.105
3108	21 CFR 314.550
3109	21 CFR 314.81
3110	21 CFR 330 (1974)
3111	21 CFR 330.1 (1975)
3112	21 CFR 330.10
3113	21 CFR 200.50 - packaging of ophthalmic 1984
3114	21 CFR 201.60 - principal display panel on package for OTC drugs 1982
3115	21 CFR 201.61 - statement of identity on principal display panel of package of OTC drugs 1982
3116	21 CFR 201.62 - net quantity of contents on package for OTC drugs 1982
3117	21 CFR 201.303 - labeling of Drug Products with Methyl Salicylate 1985
3118	21 CFR 201.303 - labeling of Drug Products with Methyl Salicylate 1986
3119	21 CFR 201.314 - pre-1986 aspirin label change (1985)
3120	21 CFR 201.314 - with aspirin label change (1986)
3121	21 CFR 207.35 (1982)
3122	21 CFR 211.22 - packaging (1982)
3123	21 CFR 211.132 - tamper resistant package for OTC (1984)
3124	21 CFR 330.1 - OTC packaging (1982)
3125	21 CFR 369 - Interpretative Statements re Warnings on drugs and devices for OTC sale (1997)
3126	21 CFR 369 Interpretative Statements re Warnings on drugs and devices for OTC sale 1998
3127	21 CFR 369 Interpretative Statements re warnings on drugs and devices for OTC sale (2008)
3128	21 CFR 369.1 - purpose of Issuance (1995)
3129	21 CFR 369.1 - purpose of Issuance (1996)
3130	21 CFR 369.1 - purpose of Issuance (1997)
3131	21 CFR 369.1 - purpose of Issuance (1998)
3132	21 CFR 369.1 - purpose of Issuance (2008)
3133	21 CFR 369.2 - definitions (1995)
3134	21 CFR 369.2 - definitions (1996)
3135	21 CFR 369.2 - definitions (1997)
3136	21 CFR 369.2 - definitions (1998)
3137	21 CFR 369.2 - definitions (2008)
3138	21 CFR 369.3 - warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C) (1995)
3139	21 CFR 369.3 - warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C) (1996)
3140	21 CFR 369.3 - warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C) (1997)
3141	21 CFR 369.3 - warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C) (1998)
3142	21 CFR 369.3 - warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C) (2008)

3143	21 CFR 369.4 - warnings suggested for drugs by formal or informal statement of policy (1995)
3144	21 CFR 369.4 - warnings suggested for drugs by formal or informal statement of policy (1996)
3145	21 CFR 369.4 - warnings suggested for drugs by formal or informal statements of policy (1997)
3146	21 CFR 369.4 - warnings suggested for drugs by formal or informal statements of policy (1998)
3147	21 CFR 369.4 - warnings suggested for drugs by formal or informal statements of policy (2008)
3148	21 CFR 369.5 - warnings required on insulin intended for OTC sale (1995)
3149	21 CFR 369.5 - warnings required on insulin intended for OTC sale (1996)
3150	21 CFR 369.5 - warnings required on insulin intended for OTC sale (1997)
3151	21 CFR 369.5 - warnings required on insulin intended for OTC sale (1998)
3152	21 CFR 369.7 - warnings required by official compendia (1995)
3153	21 CFR 369.7 - warnings required by official compendia (1996)
3154	21 CFR 369.7 - warnings required by official compendia (1997)
3155	21 CFR 369.7 - warnings required by official compendia (1998)
3156	21 CFR 369.7 - warnings required by official compendia (2008)
3157	21 CFR 369.8 - warning statements in relation to conditions for use (1995)
3158	21 CFR 369.8 - warning statements in relation to conditions for use (1996)
3159	21 CFR 369.8 - warning statements in relation to conditions for use (1997)
3160	21 CFR 369.8 - warning statements in relation to conditions for use (1998)
3161	21 CFR 369.8 - warning statements in relation to conditions for use (2008)
3162	21 CFR 369.9 - general warnings re accidental ingestion by children (2008)
3163	21 CFR 369.9 - general warnings re accidental ingestion by children (1995)
3164	21 CFR 369.9 - general warnings re accidental ingestion by children (1996)
3165	21 CFR 369.9 - general warnings re accidental ingestion by children (1997)
3166	21 CFR 369.9 - general warnings re accidental ingestion by children (1998)
3167	21 CFR 369.10 - conspicuousness of warning statements (1995)
3168	21 CFR 369.10 - conspicuousness of warning statements (1996)
3169	21 CFR 369.10 - conspicuousness of warning statements (1997)
3170	21 CFR 369.10 - conspicuousness of warning statements (1998)
3171	21 CFR 369.10 - conspicuousness of warning statements (2008)
3172	21 CFR 369.20 Warnings for labels for certain drugs (including aspirin) (1986)
3173	21 CFR 369.20 - drugs; recommended warning and caution statements (1995)
3174	21 CFR 369.20 - drugs; recommended warning and caution statements (1996)
3175	21 CFR 369.20 - drugs; recommended warning and caution statements (1997)
3176	21 CFR 369.20 - drugs; recommended warning and caution statements (1998)
3177	21 CFR 369.20 - drugs; recommended warning and caution statements (2008)
3178	21 CFR 369.21 - drugs; warning and caution statements required by regulations (1995)
3179	21 CFR 369.21 - drugs; warning and caution statements required by regulations (1996)
3180	21 CFR 369.21 - drugs; warning and caution statements required by regulations (1997)
3181	21 CFR 369.21 - drugs; warning and caution statements required by regulations (1998)
3182	21 CFR 369.21 - drugs; warning and caution statements required by regulations (2008)
3183	21 CFR 369.22 - drugs; warning and caution statements specifically required by law (1995)
3184	21 CFR 369.22 - drugs; warning and caution statements specifically required by law (1996)
3185	21 CFR 369.22 - drugs; warning and caution statements specifically required by law (1998)
3186	21 CFR 201.66 (1999)
3187	21 CFR 201.55 (2008)
3188	21 CFR, Part G 1996 Special regs for particular OTC drugs
3189	21 CFR 330.1 (2007)
3190	21 CFR 330.10 (2007)

3191	21 CFR 330.11 (2007)
3192	21 CFR 330.14 (2007)
3193	21 CFR 330.1 (2005)
3194	21 CFR 330.10 (2005)
3195	21 CFR 330.11 (2005)
3196	21 CFR 330.14 (2005)
3197	21 CFR 330.1 (2006)
3198	21 CFR 330.10 (2006)
3199	21 CFR 330.11 (2006)
3200	21 CFR 330.14 (2006)
3201	21 CFR 330.1 (2004)
3202	21 CFR 330.10 (2004)
3203	21 CFR 330.11 (2004)
3204	21 CFR 330.14 (2004)
3205	21 CFR 330.1 (2003)
3206	21 CFR 330.10 (2003)
3207	21 CFR 330.11 (2003)
3208	21 CFR 330.14 (2003)
3209	21 CFR 330.1 (2002)
3210	21 CFR 330.10 (2002)
3211	21 CFR 330.11 (2002)
3212	21 CFR 330.14 (2002)
3213	21 CFR 330.1 (2001)
3214	21 CFR 330.10 (2001)
3215	21 CFR 330.11 (2001)
3216	21 CFR 330.1 (2000)
3217	21 CFR 330.10 (2000)
3218	21 CFR 330.11 (2000)
3219	21 CFR 330.1 (1999)
3220	21 CFR 330.10 (1999)
3221	21 CFR 330.11 (1999)
3222	21 CFR 330.1 (1998)
3223	21 CFR 330.10 (1998)
3224	21 CFR 330.11 (1998)
3225	21 CFR 330.1 (1997)
3226	21 CFR 330.10 (1997)
3227	22 CFR 330.11 (1997)
3228	21 CFR 330.1 (1996)
3229	21 CFR 330.10 (1996)
3230	21 CFR 330.11 (1996)
3231	21 CFR 330.11 (1995)
3232	21 CFR 330.10 (1995)
3233	21 CFR 330 2008
3234	Medicare regs for billing
3235	June 1995 MedWatch Continuing Education
3236	MedWatch Continuing Education Article “The Clinical Impact of Adverse Event Reporting”
3237	FDA FAQs on Regulatory Process of OTC Drugs
3238	FDA Annual Adverse Drug Experience Report: 1996 (dated October 1997 CDER)

3239	FDA Guidance for Industry – Labeling OTC Human Drug Products (December 2000)
3240	Sills, et al., "Food and Drug Administration Monitoring of adverse drug reactions" (1986)
3241	Geiringer, "The Safety and Efficacy of New Drug Approval" (1985)
3242	Sills, et al., "Postmarketing Reporting of Adverse Drug Reactions to the FDA: An Overview of the 1985 FDA Guideline" (1986)
3243	Excerpts from the FDA's final rule concerning Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products published on January 24, 2006, specifically pages 1 and 37-47
3244	41 Federal Register 6908 revisions and re-codification to FDACA and Fair Packaging and Labeling Act (February 1976)
3245	21 CFR 369.22 Drugs; warning and caution statements specifically required by law (1977)
3246	21 CFR 330.10 (1984)
3247	21 CFR 314.105 (1995)
3248	21 CFR 341 (1996)
3249	21 CFR 341 (1995)
3250	21 CFR 201.63 (1995)
3251	21 CFR 201.62 (1995)
3252	21 CFR 201.61 (1995)
3253	21 CFR 201.60 (1995)
3254	21 CFR S 1.21
3255	21 CFR 314.80 (1995)
3256	21 CFR 314.81 (1995)
3257	21 CFR 330.13
3258	21 CFR 330.12
3259	21 CFR 330.5
3260	21 CFR 330.3
3261	21 CFR 330.1
3262	53 Federal Register 46204 (1988), Proposed Rule: Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) OTC tentative final monograph
3263	68 Federal Register OTC labeling (5/03)
3264	21 CFR 201.303 (1985)
3265	21 CFR 341 (1996)
3266	"Ibuprofen: Form(s) and Strength(s) Available", U.S. Food and Drug Administration.
3267	"Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (Ibuprofen)", U.S. Food and Drug Administration, Center for Drug Evaluation and Research, updated December
3268	"Drug Information: Ibuprofen", Medline Plus, U.S. National Library of Medicine / National Institutes of Health, updated Dec. 1. 2008
3269	"MedWatch Form", Form FDA 3500, U.S. Department of Health and Human Services, January 2009
3270	"What is a Serious Adverse Event", U.S. Food and Drug Administration, updated February 19, 2010, available at http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm
3271	"MedWatch: The FDA Safety Information and Adverse Event Reporting Program (Home Page)", U.S. Food and Drug Administration, updated February 20, 2010, available at http://www.fda.gov/Safety/MedWatch/default.htm
4001	L.E. Bottiger, et al., "Drug-induced Febrile Mucocutaneous Syndrome," Acta Med. Scand.; 198(3):229-233 (1975)
4002	Karch, FD, et al., "Commentary: Adverse drug reactions – a matter of opinion," Clinical Pharmacology and Therapeutics; 19:489-492 (1976)

4003	Koch-Weser J, et al., "The ambiguity of adverse drug reactions," European Journal of Clinical Pharmacology; 11:75-78 (1977)
4004	Peter Sternlieb, M.D., et al., "Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen," New York State Journal of Medicine (1978)
4005	Robert Temple, et al., "Adverse Effects of Newly Marketed Drugs," NEJM; 300(18): 1046-1047 (1979)
4006	CDC, Follow-up on Reye Syndrome – United States, Morbidity and Mortality Weekly Report, 29:321-322 (1980)
4007	Reye's Syndrome – Epidemiological Considerations, Lancet 1(8278):941-943 (1982)
4008	CDC, National Surveillance for Reye Syndrome, 1981: Update, Reye Syndrome and Salicylate Usage, Morbidity and Mortality Weekly Report, 31(5):53-60 (1982)
4009	B.U. Wintroub, R.S. Stern, "Ch. 6: Cutaneous Drug Reactions," Current Perspectives in Immunodermatology: 75-97 (1984)
4010	Robert Stern, et al., "An Expanded Profile of Cutaneous Reactions to NSAIDs," JAMA; 252(11):1433-1437 (1984)
4011	George L. Royer, et al., "Safety Profile: Fifteen Years of Clinical Experience with Ibuprofen," American Journal of Medicine (1984)
4012	William O'Brien, et al, "Rare Adverse Reactions to Nonsteroidal Anti-inflammatory Drugs," J. Rheumatology; 12(1):13-17 (1985)
4013	Louik C, et al., "A study of adverse reaction algorithms in a drug surveillance program," Clinical Pharmacology and Therapeutics; 38:183-187 (1985)
4014	Bigby, et al. "Cutaneous reactions to nonsteroidal anti-inflammatory drugs. A review," J Am Acad Dermatol; 12: 866-876 (1985)
4015	Jean-Claude Guillaume, Jean-Claude Roujeau, et al., "The Culprit Drugs in 87 Cases of Toxic Epidermal Necrolysis (Lyell's Syndrome)," Arch Dermatology 123:1166-1170 (1987)
4016	Jean-Claude Roujeau, et al., "Genetic Susceptibility to TEN," Arch. Dermatology; 123:1171-1173 (1987)
4017	Jean Claude Roujeau, "Clinical Aspects of Skin Reactions to NSAIDs," Scand. J. Rheumatology; (Suppl. 65):131-134 (1987)
4018	Robert Stern, et al., "Adverse Drug Reactions: Reporting and Evaluating Cutaneous Reactions," Adv. Dermatology; 2: 3-18 (1987)
4019	Everett Dillman, "Episodic Conjunctival Inflammation after SJS," Ophthalmology; 95(4): 453-62
4020	Jacklyn Stotts, "Fenoprofen-induced TEN," J. Am. Acad. Dermatol.;18(4) (1988)
4021	Valerie B. Laing, et al., "Pemphigoid-like bullous eruption related to ibuprofen," J. Amer. Acad. Dermatology; 19(1): 91-94 (1988)
4022	Robert Stern, et al., "Usefulness of case report literature in determining drugs responsible for TEN," J. Amer. Acad. Dermatology;(2)1:317-322 (1989)
4023	Michael Bigby and Robert Stern, "Allergic Cutaneous Reactions to Drugs," Primary Care; 16(3): 713-727 (1989)
4024	Philip D. Walson, et al., "Ibuprofen, acetaminophen, and placebo treatment of febrile children," Clin. Pharmacol. Ther.; 46: 9-17 (1989)
4025	Chan, et al, The Incidence of Erythema Multiforme, Stevens-Johnson Syndrome, and Toxic Epidermal Necrolysis, Arch Dermatol: 126: 43-47 (1990)
4026	L. Naldi, et al., "Incidence of Toxic Epidermal Necrolysis in Italy," Arch Dermatol; 126:1103-1104 (1990)
4027	Jean Claude Roujeau, et al., "Toxic Epidermal Necrolysis (Lyell Syndrome)," Arch Dermatol; 126:37-42 (1990)

4028	Jean Claude Roujeau, et al., "Toxic Epidermal Necrolysis (Lyell Syndrome)," J. Amer. Acad. Dermatology; 23: 6, Part 1 (1990)
4029	David A. Kessler, MD, JD, Wayne L. Pines, "The Federal Regulation of Prescription Drug Advertising and Promotion," JAMA; 264(18): 2409-2415 (1990)
4030	Strom, et al., A Population-Based Study of Stevens-Johnson Syndrome, Arch. Dermatol. 127: 831-838 (1991)
4031	Schopf, et al., Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome, Arch. Dermatol. 127: 839-842 (1991)
4032	Brian Strom, Robert Stern, et al., "Using a Claims Database to Investigate Drug-Induced Stevens-Johnson Syndrome," Statistics in Medicine; 10: 565-576 (1991)
4033	Levenson, DE, et al. "Cutaneous manifestations of adverse drug reactions," Immunology Clinics of North America; 11: 493-507 (1991)
4034	Samuel L. Moschella, et al. , "Drug Eruptions," Dermatology, 3rd edition, Chapter 23 (1992)
4035	GISED, "Cutaneous reactions to analgesic-antipyretics and nonsteroidal anti-inflammatory drugs. Analysis of reports to the spontaneous reporting system of the Gruppo Italiano Studi Epidemiologici in Dermatologia," Dermatology; 186(3):164-169 (1993)
4036	S.M. Halpern, et al., "Ibuprofen Toxicity. A Review of Adverse Reactions and Overdose," Adv. Drug Rxn. Toxic. Review; 12(2):107-128 (1993)
4037	Bastuji-Garin, et al., "Clinical Classification of Cases of Toxic Epidermal Necrolysis, Stevens-Johnson Syndrome, and Erythema Multiforme," Arch Dermatol; 129: 92-96 (1993)
4038	O. Correia, J.C. Roujeau, et al., "Evolving Pattern of Drug-Induced Toxic Epidermal Necrolysis," Dermatology; 186: 32-37 (1993)
4039	Jean-Claude Roujeau, MD, "Drug-Induced Toxic Epidermal Necrolysis," Clinics in Dermatology; 11:493-500 (1993)
4040	Michel Auriche, et al., "Does Proof of Causality Ever Exist in Pharmacovigilance?," Drug Safety; 9(3): 230-235 (1993)
4041	Jean-Claude Roujeau, et al., "Toxic epidermal necrolysis: An expanding field of knowledge," J. Amer. Acad. Dermatology; 31: (301-302) (1994)
4042	S.M. Halpern, et al., "Cutaneous Toxicity of Ibuprofen," Arch. Derm; 130: 259-260 (1994)
4043	Jean Claude Roujeau, MD and Robert S. Stern, MD, "Severe Adverse Cutaneous Reactions to Drugs," The New England Journal of Medicine; 331(19):1272-1285 (1994)
4044	"An Assessment of the Safety of Pediatric Ibuprofen," by SM Lesko and AA Mitchell, JAMA, March 22/29, (1995)
4045	Power, et al, Ophthalmology, "Analysis of the Acute Ophthalmic Manifestations of the EM/SJS/TEN Disease Spectrum," Vol. 102, pp. 1669-1676 (1995)
4046	Roujeau, et al., "Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis," New England Journal of Medicine 333:1600 (1995)
4047	Haudrey Assier, et al., "Erythema Multiforme with Mucous Membrane Involvement and Stevens-Johnson Syndrome Are Clinically Different Disorders with Distinct Causes," Arch Dermatol; 131: 539-543 (1995)
4048	Steven Manders, "Serious and Life-Threatening Drug Eruptions," American Family Physician: 1865-1872 (1995)
4049	Judith Parsells Kelly, et al., "An International Collaborative Case-Control Study of Severe Cutaneous Adverse Reactions (SCAR). Design and Methods," Journal of Clinical Epidemiology; Vol. 48 (9): 1099-1108 (1995)
4050	David Gaist, et al., "Spontaneous Reports of Drug-Induced Erythema Multiforme, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Denmark 1968-1991," Pharmacoepidemiology and Drug Safety; 5: 79-86 (1996)

4051	PDR Guide to Drug Interactions - 1996
4052	D. Salomon, et al., "Five Cases of TEN Treated by Intravenous Immunoglobulins with Favorable Results," Annales de Dermatologie et de Venereologie; 124:216-217 (1997)
4053	RD DeShazo & SF Kemp, "Allergic Reactions to Drugs and Biologic Agents," JAMA 278(22):1895-1906 (1997)
4054	K.D. Rainsford, et al., "Ibuprofen and Paracetamol: Relative Safety in Non-prescription Dosages," J. Pharm. Pharmacol.; 49:345-376 (1997)
4055	PDR Guide to Drug Interactions - 1997
4056	Isabelle Viard, "Inhibition of TEN by Blockade of CD95 with Human Intravenous Globulin," Science; 282 (1998)
4057	Maya Srivastava, et al., "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child," Gastroenterology; 15(3): 743-746 (1998)
4058	David S. Becker, "Toxic Epidermal Necrolysis," Lancet; 353: 1417-1420 (1998)
4059	Paul, CN, et al., J. Burn Care & Rehab;19:321-333 (1998)
4060	Bell, MJ, et al., "A case of Stevens-Johnson syndrome associated with oxaprozin therapy," J. Rheumatology; 25:2026-2028 (1998)
4061	PDR Companion Guide Excerpt - 1998
4062	Peter Fritsch, et al., "Stevens-Johnson Syndrome-Toxic Epidermal Necrolysis," Fitzpatrick's Dermatology in General Medicine, 5th Ed. Chapter 59 (1999)
4063	E. Ashraf, et al., "Safety profile of ibuprofen suspension in young children," Inflammopharmacology; 7(3): 219-225 (1999)
4064	Robert Stern, et al., "Chapter 140: Cutaneous Reactions to Drugs," Fitzpatrick's Dermatology in General Medicine; 5th Ed. (1633-1642) (1999)
4065	R.L. Sheridan, et al., "Management of Severe TEN in Children," J. Burn Care & Rehabilitation; 497-500 (1999)
4066	Carucci, JA, et al., Int. J. Dermatology; 38: 228-239 (1999)
4067	PDR Companion Guide Excerpt - 1999
4068	Robert Stern, "Improving the Outcome of Patients with TEN and SJS," Arch. Dermatol.; 136: 410-411 (2000)
4069	Pierre Wolkenstein, et al., "Toxic Epidermal Necrolysis," Inpatient Dermatology; 18(3): 485-495 (2000)
4070	Ignacio Garcia-Doval, Jean Claude Roujeau, et al., "Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome," Arch. Dermatology; 136: 323-327 (2000)
4071	Craig K. Svensson, et al., "Cutaneous Drug Reactions," Pharmacological Reviews; 53(3):357-379 (2000)
4072	Mihaela Ringheanu, et al., "Toxic Epidermal Necrolysis in Children – An Update," Clinical Pediatrics; 687-694 (2000)
4073	PDR Companion Guide Excerpt - 2000
4074	Jean-Paul Fagot, et al., "Nevirapine and the risk of SJS or TEN," AIDS; 15(14): 1843-48 (2001)
4075	Marcus Spies, MD; et al., "Treatment of Extensive Toxic Epidermal Necrolysis in Children," Pediatrics; 108(5):1162-1168 (2001)
4076	Michael Morelli, et al., "Stevens-Johnson Syndrome and Cholestatic Hepatitis," Digestive Diseases and Sciences; 46(11): (2385-2388) (2001)
4077	PDR Companion Guide Excerpt - 2001
4078	Robert L. Sheridan, et al., "Long-Term Consequences of Toxic Epidermal Necrolysis in Children," Pediatrics;109(1): 74-78 (2002)
4079	R Forman, G Koren, N Shear, "Erythema Multiforme, SJS, and TEN in Children: A Review of 10 Years' Experience," Drug Safety; 25(13): 965-972 (2002)

4080	Ariane Auquier-Dunant, et al., "Correlations Between Clinical Patterns and Causes of Erythema Multiforme Majus, Stevens-Johnson Syndrome, and Toxic Epidermal Necrolysis," Arch. Dermatol.;138:1019-1024 (2002)
4081	Pierre Dominique Ghislain M.D. and Jean-Claude Roujeau, M.D., "Treatment of Severe Drug Reactions: Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Hypersensitivity Syndrome" Dermatol Online J 8(1) (2002)
4082	PDR Companion Guide Excerpt - 2002
4083	Mockenhaupt, et al., "The Risk of Stevens- Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Anti-inflammatory Drugs: A Multinational Perspective," J Rheumatology, 30:2234-40 (2003)
4084	Jennifer Trent, "Analysis of Intravenous Immunoglobulin for the Treatment of TEN using SCORTEN," Arch Dermatol; 139 (2003)
4085	Christa Prins, et al., "Treatment of Toxic Epidermal Necrolysis with High-Dose Intravenous Immunogobulins," Arch. Derm; 139: 26-32 (2003)
4086	PDR Companion Guide Excerpt - 2003
4087	Jeffrey K. McKenna, et al., "Dermatologic drug reactions," Immunol Allergy Clin N Am 24; 399-423 (2004)
4088	Mario DiPascuale, et al., "Correlation of Corneal Complications with Eyelid Cicatricial Pathologies in Patients with SJS and TEN," Ophthalmology; 112(5):904-912 (2004)
4089	M. Taghian, et al., "Acute Vanishing Bile Duct Syndrome after Ibuprofen Therapy in a Child," J. Pediatrics; 273-276 (2004)
4090	PDR Companion Guide Excerpt - 2004
4091	M.-S. Lin; Y.-S. Dai; R.-F. Pwu; Y.-H. Chen; N.-C. Chang, "Brief Communication: Risk estimates for drugs suspected of being associated with Stevens-Johnson syndrome and toxic epidermal necrolysis: a case- control study," Internal Medicine Journal; Vol. 35: 188-190 (2005)
4092	Encan Arca, "A 2-year-old Girl with SJS/TEN Treated with Intravenous Immunoglobulin," Ped. Dermatol.; 22(4):317-330 (2005)
4093	Letko, et al., "SJS and TEN: a review of the literature," Ann. Allergy Asthma Immunol; 94(4):419-436 (2005)
4094	Mockenhaupt, et al., "Risk of SJS and TEN in new users of antiepileptics," Neurology; 64(7):1134-1138 (2005)
4095	Shilad, A., et al., "Human Immunodeficiency Virus, Pregnancy, and SJS," Obstet Gynecol.; 105(5):1254-1256 (2005)
4096	Louis LaGrenade, "Comparison of Reporting SJS and TEN in Association with Selective COX-2 Inhibitors," Drug Safety; 28(10):917-924 (2005)
4097	"Stevens-Johnson syndrome," Griffith's Five-Minute Clinical Consult (2005)
4098	Lars E. French, et al., "Use of intravenous immunoglobulin in toxic epidermal necrolysis and Stevens-Johnson syndrome: Our current understanding," International Immunopharmacology; 6: 543-549 (2005)
4099	Robert Stern, "Severe Skin Reactions and Commonly Prescribed Medicines – SJS and TEN," Johns Hopkins Newsletter – Early Recognition & Warning Signs of Severe Skin Reactions (2005)
4100	French, L., et al., "Erythema Multiforme, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis," in Bolognia, J, et al. (Eds.), Dermatology 2nd Edition, Ch. 21, Mosby (2008).
4101	C. Everett Dillman, et al., "Stevens-Johnson Syndrome," http://www.emedicine.com/oph/topic268.htm (June 13, 2005)
4102	Maher Nasser, et al., "Intravenous Immunoglobulin for Treatment of Toxic Epidermal Necrolysis," Am. J. of the Med. Sciences; 329(2):95-98 (2005)
4103	Vol 1, Chapter 58, p. 691-702 (2005)

4104	PDR Companion Guide Excerpt - 2005
4105	Paul A. Greenberger, "Drug allergy," J. Aller. Clin. Immunol; 117(2): 464-470 (2006)
4106	Jean-Claude Roujeau, "Immune Mechanisms in Drug Allergy," Allergology International; 55(27-33) (2006)
4107	Nicole Mittman, "Intravenous Immunoglobulin Use in Patients with TEN and SJS," Am. J. Clin. Dermatol; 7(6): 359-368 (2006)
4108	Sarah Guegan, et al., "Performance of the SCORTEN During the First Five Days of Hospitalization to Predict the Prognosis of TEN," Journal of Investigative Dermatology; 126: 272-276 (2006)
4109	Barzin Khalili, et al., "Pathogenesis and Recent Therapeutic Trends in SJS and TEN," Annals of Allergy, Asthma & Immunology (2006)
4110	C. Lonjou, et al., "A Marker for SJS . . .: Ethnicity Matters," Pharmacogenomics Journal; 6: 265-268 (2006)
4111	Lars E. French, "Toxic Epidermal Necrolysis and Stevens-Johnson syndrome: Our Current Understanding," Allergology International; 55:9-16 (2006)
4112	Deborah Layton, et al., "Serious Skin Reactions and Selective COX-2 Inhibitors," Drug Safety; 29(8): 687-696 (2006)
4113	PDR Guide to Drug Interactions - 2006
4114	L.W. Yip, "Ocular Manifestations and complications of SJS and TEN: an Asian series," Allergy; 62: 527-531 (2007)
4115	Nicola A. Clayton, et al., "Management of Dysphagia in Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS)," Dysphagia; 22:187-192 (2007)
4116	Frederick A. Pereira, et al., "Toxic epidermal necrolysis," J. Am. Acad. Derm.; 56(2): 181-200 (2007)
4117	Mirjana Ziemer, MD, "Cutaneous Adverse Reactions to Valdecoxib Distinct from Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis," Arch. Dermatol; 143:711-716 (2007)
4118	J. Dore and R. Salisbury, "Morbidity and Mortality of Mucocutaneous Diseases in the Pediatric Population at a Tertiary Care Center," J. Burn Care & Rehab.; 28(6):1-5 (2007)
4119	Yi-Sheng Chang, et al., "Erythema Multiforme, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis," Cornea; 26(2): 123-129 (2007)
4120	Ronni Wolf, et al., "In the Pursuit of Classifying Severe Cutaneous Adverse Reactions," Clinics in Dermatology; 25: 348-349 (2007)
4121	Manuela Neuman, et al., "Apoptosis in Ibuprofen-Induced SJS," Translational Research; 149(5): 254-259 (2007)
4122	Mayumi Ueta, et al., "Strong Association Between HLA-A*0206 and SJS in the Japanese," American Journal of Ophthalmology; 143(2):367-368 (2007)
4123	Yumiko Yamane, "Analysis of SJS and TEN in Japan from 2000 to 2006," Allergology International; 56(4): 419-425 (2007)
4124	Sami L. Bahna, et al., "New concepts in the management of adverse drug reactions," Allergy and Asthma Proceedings; 28(5): 517-524 (2007)
4125	Wen-Hung Chung, et al., "Human leukocyte antigens and drug hypersensitivity," Drug Allergy (2007)
4126	PDR Guide to Drug Interactions - 2007
4127	Mockenhaupt, et al., "Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: Assessment of Medication Risks with Emphasis on Recently Marketed Drugs. The EuroSCAR-Study," Journal of Investigative Dermatology, 128, 35-44 (2008)
4128	M. Patel Raksha, et al., "Clinical study of cutaneous drug eruptions in 200 patients," Indian J. Dermatol Venerol Leprol; 74:80 (2008)
4129	Jurgen Schneck, Jean-Claude Roujeau, Maja Mockenhaupt, et al., "Effects of treatments on the mortality of Stevens-Johnson syndrome and toxic epidermal necrolysis: A retrospective study on patients included in the prospective EuroSCAR study," J. Amer. Acad. Dermatology 58: 1 (2008)

4130	Mayumi Ueta, et al., "Association of Combined IL-13/IL-4R Signaling Pathway Gene Polymorphism with SJS Accompanied by Ocular Surface Complications," Investigative Ophthalmology & Visual Science; 49(5): 1809-1814 (2008)
4131	Maymie Ueta, et al., Association of Fas Ligand Gene Polymorphism With SJS," Br. J. Ophthalmology; 92:989-991 (2008)
4132	Theresa Mayes, et al., "Energy Requirements of Pediatric Patients with SJS and TEN," Nutrition in Clinical Practice; 23(5):547-550 (2008)
4133	Junko Murata, et al., "Increased Soluble Fas Ligand Levels in Patients with SJS and TEN Preceding Skin Detachment," J. Allergy Clin. Immunol; 122(5): 992-1000 (2008)
4134	Mayumi Ueta, et al., "HLA Class I and II Gene Polymorphisms in SJS with Ocular Complications in Japanese," Molecular Vision; 14:550-555 (2008)
4135	Vinod K. Sharma, et al., "SJS, TEN and SJS-TEN Overlap: A Retrospective Study of Causative Drugs and Clinical Outcome," Indian J. Dermatol. Venererol. Leprol; 74:238-49 (2008)
4136	Sook Jung Yun, et al., "Serum Lactate Dehydrogenase Is a Novel Marker for the Evaluation of Disease Severity in the Early Stage of TEN," Dermatology; 217:254-259 (2008)
4137	Nahoko Keniwa, et al., "HLA-B locus in Japanese patients with anti-epileptics and allopurinol-related Stevens-Johnson syndrome and toxic epidermal necrolysis," Pharmacogenomics; 9(11): 1617-16221 (2008)
4138	Zahra Pourpak, et al., "Understanding Adverse Drug Reactions and Drug Allergies: Principles, Diagnosis and Treatment Aspects," Recent Patents on Inflammation & Allergy Drug Discovery; 2:24-37 (2008)
4139	Andrea T. Borchers, et al., "Stevens-Johnson syndrome and toxic epidermal necrolysis," Autoimmunity Reviews: 7: 598-605 (2008)
4140	PDR Guide to Drug Interactions - 2008
4141	Riichiro Abe, "TEN and SJS: Soluble Fas Ligand Involvement in the Pathomechanisms of These Diseases," Journal of Dermatological Science; 52: 151-159 (2008)
4142	Harilaos Brilakis, et al., "Erythema Multiforme, Stevens-Johnson Syndrome, and Toxic Epidermal Necrolysis," Cornea, 2nd Edition
4143	Hynes, et al., "Controversy in the Use of High Dose Systemic Steroids in the Acute Care of Patients with Stevens-Johnson Syndrome," International Ophthalmology Clinics (or North American Ophthalmology Clinics)
4144	Incidence and Prevalence Database
4145	All medical/scientific literature reviewed, relied upon, used in deposition or cited in depositions of experts in this matter
4146	Bruce Wintroub M.D. and Robert Stern, M.D., "Cutaneous drug reactions: Pathogenesis and clinical classification." J. Amer. Acad. Derm. 1985; 13(2): 167-177
4147	Joseph Dooley, " The Value of Laboratory Monitoring for Children with Epilepsy." Seminars in Pediatric Neurology 1994; 1(2): 131-135
4148	O. Besag, et al., "Long-term safety and efficacy of lamotrigine (Lamictal) in pediatric patients with epilepsy." Seizure 1997; 6:51-56
4149	Alan H. Guberman, "Lamotrigine-Associated Rash: Risk/Benefi Considerations in Adults and Children." Epilepsia 1999; 40(7): 985-991
4150	J. Parsons, et al., "Toxic Epidermal Necrolysis." International Journal of Dermatology 1992; 31(11):749-68.
4151	I. Alam, et al., "Vanishing Bile Duct Syndrome Temporally Associated with Ibuprofen Use." American Journal of Gastroenterology 1996; 91(8): 1626-1630

4152	Mockenhaupt, et al., "Evaluation of non-steroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants as risk factors for Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)." Pharmacoepidemiology and Drug Safety 1996
4153	N. Bachot, J. Roujeau, et al., "Intravenous Immunoglobulin Treatment for Stevens- Johnson Syndrome and Toxic Epidermal Necrolysis." Arch. Dermatology 2003; 139: 33-36.
4154	Wolkenstein, et al., "Drug-Induced Toxic Epidermal Necrolysis." Clinics in Dermatology 1998; 16:399-409.
4155	J. Roujeau, et al., "Vulvovaginal Sequelae in toxic Epidermal Necrolysis." Jour of Reproductive Med. 1997; 42: 153-156.
4156	N. Levi, M. Mockenhaupt., "Medications as Risk Factors of Stevens-Johnson Syndrome and toxic Epidermal Necrolysis n Children: A pooled Analysis." Pediatrics 2009
4157	M. Mockenhaupt, "Epidemiology and Causes of Severe Cutaneous Averse Reactions to Drugs." Drug Hypersensitivity 2007; 18-31.
4158	S. Halevy, M. Mockenhaupt, "Allopurinol is the most common cause of Stevens-Johnson syndrome and toxic epidermal necrolysis in Europe and Israel." J. Am. Acad. Dermatol. 2008; 58(1): 25-32
4159	Bachot, et al., "Differential Diagnosis of Severe Cutaneous Drug Eruptions." Am J Clin Dermatol. 2003; 4(8):561-72
4160	Fournier, et al., "Toxic Epidermal Necrolysis Associated with Mycoplasma pneumoniae Infection." Eur. J. Clin. Microbiol. Infect. Dis. 1995; 14:558-559
4161	Brown K.M., et al., Journal of Burn Care and Rehab, "Toxic Epidermal Necrolysis: Does Immunoglobulin Make a Difference?", pp. 81-88, (Jan/Feb 2004)
4162	Shortt R., et al., Journal of Burn Care and Rehab, "Intravenous Immunoglobulin Does Not Improve Outcome in Toxic Epidermal Necrolysis", pp. 246-254, (May/June 2004).
4163	Faye O. and Roujeau J., Drugs, "Treatment of Epidermal Necrolysis with High-Dose Intravenous Immunoglobulins (IVIg)", Vol. 65, No. 15, pp. 2085-2090, (2005)
4164	Trent J., et al., Arch Dermatol, "Analysis of Intravenous Immunoglobulin for the Treatment of Toxic Epidermal Necrolysis Using SCORTEN", Vol. 139, pp. 39-43, (Jan. 2003).
4165	Prins C., Arch Dermatol, "Treatment of Toxic Epidermal Necrolysis with High-Dose Intravenous Immunoglobulins", Vol. 139, pp. 26-32, (Jan. 2003)
4166	Chart of The German Registry on Severe Skin Reactions (Dokumentationszentrum schwerer Hautreaktionen) Cases: 1990-2009
4167	Rockhill B., et al., Amer Journal of Public Health, "Use and Misuse of Population Attributable Fractions", Vol. 88, No. 1, pp. 15-19, (Jan. 1998)
4168	Nasser M., et al., Amer Jour Med Sci, "Intravenous Immunoglobulin for Treatment of Toxic Epidermal Necrolysis", Vol. 329, No. 2, pp. 95-98, (Feb. 2005)
4169	Campione E., et al., Acta Derm Venereol, "High-dose Intravenous Immunoglobulin for Severe Drug Reactions: Efficacy in Toxic Epidermal Necrolysis", Vol. 83, pp. 430-432, (2003)
4170	Tristani-Firouzi P., et al., J Amer Acad Dermatol, "Treatment of toxic epidermal necrolysis with intravenous immunoglobulin in children", Vol. 47, No. 4, pp. 548-552, (Oct. 2002)
4171	Stella M., et al., Burns, "Experience with high dose intravenous immunoglobulins and topical conservative approach in the treatment of TEN", Vol. 33S, pp. S155-S156, (2007)
4172	Mittmann N., et al., Amer Jour Clin Dermatol, "Intravenous Immunoglobulin Use in Patients with Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome", Vol. 7, No. 6, pp. 359-368, (2006)
4173	Tan A., et al., Clinical and Experimental Dermatology, "Treatment of toxic epidermal necrolysis in AIDS with intravenous immunoglobulins", Vol. 28, pp. 269-271, (2003)
4174	Arca E, et al., Pediatric Dermatology, "A 2-Year-Old Girl with Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis Treated with Intravenous Immunoglobulin", Vol. 22, No. 4, pp. 317-320 (July/Aug. 2005)

4175	Mockenhaupt M., Der Hautarzt, "Schlusswort", Vol. 51, p. 107 (2000)
4176	Al-Mutairi N., et al., International Journal of Dermatology, "Prospective, noncomparative open study from Kuwait of the role of intravenous immunoglobulin in the treatment of toxic epidermal necrolysis", Vol. 43, pp. 847-851, (2004)
4177	Lissia M., et al., British Jour Plastic Surgery, "Intravenous immunoglobulins and plasmapheresis combined treatment in patients with severe toxic epidermal necrolysis: preliminary report", Vol. 58, pp. 504-510, (2005)
4178	Mangla K. , et al., Indian J Dermatol Venereol Leprol, "Efficacy of low dose intravenous immunoglobulins in children with toxic epidermal necrolysis: An open uncontrolled study", Vol. 71, No. 6, pp. 398-400, (Nov./Dec. 2005)
4179	Mukasa Y. and Craven N., Postgrad Med Jour, "Management of toxic epidermal necrolysis and related syndromes", Vol. 84, pp. 60-65, (2008)
4180	International Committee of Medical Journal Editors, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication", www.icmje.org, pp. 1-16 (Oct. 2008)
4181	Journal of Burn Care & Research, "Authorship Responsibility, Financial Disclosure, and Copyright Transfer" Form
4182	Journal of Burn Care & Research, "Online Submission and Review System" Policy
4183	Revuz J., et al., Arch Dermatol, "Toxic Epidermal Necrolysis: Clinical Findings and Prognosis Factors in 87 Patients", Vol. 123, No. 9, pp. 1160-1165 (1987)
4184	Mockenhaupt M., Severe Cutaneous Adverse Reaction. In Burgdorf WHC, Plewig G, Wolff HH, Landthaler M, Braun-Falco O (Eds.) Dermatology and Venerology 3d edition, Ch. 34, pp. 473-484, Springer Medicine Verlag, Heidelberg (2008)
4185	Mockenhaupt M., Journal of the German Society of Dermatology (JDDG), "Severe drug-induced skin reactions: clinical patterns, diagnostics and therapy", Vol. 7, pp. 142-162, (2009)
4186	Mockenhaupt M., Stevens-Johnson syndrome and toxic epidermal necrolysis. In Revuz J, Roujeau JC, Kerdel F, Allanor L (Eds.) Life Threatening Dermatoses and Emergencies in Dermatology 1st edition, Ch. 3, Springer-Verlag (2009)
4187	Broadbent R., Rocky Mountain Med Jour, "Stevens-Johnson disease presenting with pneumothrorax", Vol. 64, pp. 69-72 (Oct. 1967)
4188	Chang, A., et al., Pediatric Radiol, "Post-infectious bronchiolitis obliterans: clinical, radiological and pulmonary function sequelae", Vol. 28, pp. 23-29 (1998)
4189	Colom A., et al., Thorax, "Risk factors for the development of bronchiolitis obliterans in children with bronchiolitis", Vo. 61, pp. 503-506, (2006)
4190	Date H., et al., Journal of Thoracic and Cardiovascular Surgery, "Living-donor lobar lung transplantation for bronchiolitis obliterans after Stevens-Johnson syndrome", Vol. 123, No. 2, pp. 389-391 (Feb. 2002)
4191	Edell, D., et al., Pediatrics, "Unusual Manifestation of Stevens-Johnson Syndrome Involving the Respiratory and Gastrointestinal Tract", Vol. 89, No. 3, pp. 429-432 (March 1992)
4192	Edwards, C., et al., Thorax, "Mycoplasma pneumoniae, Stevens-Johnson syndrome, and chronic obliterative bronchitis", Vol. 38, pp. 867-869, (1983)
4193	Gross, T., et al., Clinics in Chest Medicine, "Noninfectious Pulmonary Disease Masquerading as Community-Acquired Pneumonia", Vol. 12, No. 2, pp. 363-393, (June 1991)
4194	Jones, M., et al., Pediatric Pulmonology, "Post-Infectious Bronchiolitis Obliterans", Vol. 26, pp. 64-65, (2004)
4195	Kamada, N., et al., Journal of Dermatology, "Chronic pulmonary complications associated with toxic epidermal necrolysis: Report of a severe case with anti-Ro/SS-A and a review of the published work", Vol. 33, pp. 616-622, (2006)

4196	Kim, C., et al., CHEST, "Bronchiolitis Obliterans in the 1990s in Korea and the United States", Vol. 120, No. 4, pp. 1101-1106 (Oct. 2001)
4197	Kim, M. and Lee, K., Pediatr Radiol, "Bronchiolitis obliterans in children with Stevens-Johnson syndrome: follow-up with high resolution CT", Vol. 26, pp. 22-25, (1996)
4198	McIvor, R., et al., Journal of Burn Care & Rehab, "Acute and Chronic Respiratory Complications of Toxic Epidermal Necrolysis", Vol. 17, No. 3, pp. 237-240, (May/June 1996)
4199	Penn, C. and Liu, C., Clinics in Chest Medicine, "Bronchiolitis Following Infection in Adults and Children", Vol. 14, No. 4, pp. 645-654, (Dec. 1993)
4200	Ringheanu, M. and Laude, T., Clinical Pediatrics, "Toxic Epidermal Necrolysis in Children-An Update", Vol. 39, pp. 687-694, (Dec. 2000)
4201	Roupe, G., et al., Int. Archs Allergy appl. Immun., "Toxic Epidermal Necrolysis with Extensive Mucosal Erosions of the Gastrointestinal and Respiratory Tracts", Vol. 80, pp. 145-151, (1986)
4202	Smith, K. and Fan, L., Thorax, "Insights into post-infectious bronchiolitis obliterans in children", Vol. 61, pp. 462-463, (2006)
4203	Stitt, V., Journal of the National Medical Association, "Stevens-Johnson Syndrome: A Review of the Literature", Vol. 80, No. 1, pp. 104-108, (1988)
4204	Sugino, K., et al., Journal of the Japanese Respiratory Society, "An autopsy case of obliterative bronchiolitis associated with Stevens-Johnson syndrome", Vol. 44, No. 7, pp. 511-516, (July 2006)
4205	Tsunoda, N., et al., CHEST, " Rapidly Progressive Bronchiolitis Obliterans Associated with Stevens-Johnson Syndrome", Vol. 98, No. 1, pp. 243-245, (July 1990)
4206	Vilchez, R., et al., American Journal of Transplantation, "Infectious Etiology of Bronchiolitis Obliterans: The Respiratory Viruses Connection - Myth or Reality?", Vol. 3, pp. 245-249, (2003)
4207	Virant, F., et al., Clinical Pediatrics, "Multiple Pulmonary Complications in a Patient with Stevens-Johnson Syndrome", Vol. 3, No. 7, pp. 412-414, (July 1984)
4208	Whyte, K. and Williams, G., Thorax, "Bronchiectasis after mycoplasma pneumonia", Vol. 39, pp. 390-391, (1984)
4209	Yatsunami, J., et al., Internal Medicine, "Chronic Bronchobronchiolitis obliterans Associated with Stevens-Johnson Syndrome", Vol. 34, No. 8, pp. 772-775, (Aug. 1995)
4210	Fox, J., *Bites: Insect, Animal, and Human.* In Fox., J. (Ed.), Primary Health Care of Infants, Children and Adolescents 2nd Ed., Ch. 37, Mosby Publishing (2002)
4211	Osborn, L.M., et al. (Eds.), Pediatrics 1st Ed., Mosby Publishing (2005)
4212	Reisman, R., *Allergies to Stinging Insects.* In Grammer, L., et al. (Eds.), Patterson's Allergic Diseases 7th Ed., Ch. 15, Lippincott, Williams & Wilkins (2009)
4213	Nasir, L., *Bites and Stings* . In David, A., et al. (Eds.) Family Medicine: Principals and Practice 6th Ed., Ch. 47, Springer-Verlag (2003)
4214	Kasper, D., et al. (Eds.), *Hymenoptera Stings* in Harrison's Principles of Internal Medicine 16th Ed., pp. 2605-2606, McGraw Hill Professional (2004)
4215	Rakel, R., *Emergency Medicine: Hymenopterans* in Textbook of Family Practice 6th Ed., Ch. 37, Saunders (2002)
4216	Goldman, L. and Ausiello, D. , *Hymenoptera* in Cecil Textbook of Medicine 22nd Ed., Ch. 406, Saunders (2004)
4217	Burns, C., et al. (Eds), *Hymenoptera* in Pediatric Primary Care: A Handbook for Nurse Practitioners 3rd Ed., Ch. 40, Saunders (2004)
4218	Behrman, R., et al. (Eds) Nelson Textbook of Pediatrics 16th Ed., pp. 2043-2044, W. B. Saunders Company (2000)
4219	Golden, D., *Allergic Reactions to Insect Stings* . In Rakel, R. and Bope, E. (Eds.), Conn's Current Therapy 2009, Saunders (2008)

4220	Schwartz, M., *Snake and Insect Bites* in The 5-Minute Pediatric Consult 3rd Ed., Lippincott Williams & Wilkins (2003)
4221	Schmidt, J., *Hymenopteran Venoms: Striving Towards the Ultimate Defense against Vertebrates*. In Evans. D and Schmidt, J. (Eds.), Insect Defenses: Adaptive Mechanisms and Strategies of Prey and Predators, Ch. 14, State University of New York Press (1990)
4222	Starr, CK., J. Entomol. Sci., "A Simple Pain Scale for Field Comparison of Hymenopteran Stings," Vol. 20, No. 2, pp. 225-232 (Apr. 1985)
4223	Stern, RS, Johns Hopkins Newsletter, "Early Recognition and Warning Signs of Severe Skin Reactions", No. 2 of 4 (May 2005)
4224	Teper, AM, et al., Am J Respir Crit Care Med, "Association Between HLA and the Incidence of Bronchiolitis Obliterans (BO) in Argentina", Vol. 169, p. A382 (2004)
4225	Ghislain, PD and Roujeau, JC, Dermatology Online, "Treatment of Severe Drug Reactions: SJS/TEN/and Hypersensitivity Syndrome", Vol. 8, No. 1, p. 5 (2002)
4226	Zalloua PA, et al., J Clinical Endocrin & Metab, "Type-2 Diabetes Family History Delays the Onset of Type-1 Diabetes", Vol. 87, No. 7, pp. 3192-3196 (2002)
4227	Moonnumakal SP and Fan LL, Curr Opin Pediatr, "Bronchiolitis Obliterans in Children", Vol. 20, pp. 272-278 (2008)
4228	Bakirtas A., et al., Pediatric Dermatol, "Bronchiolitis Obliterans: A Rare Chronic Pulmonary Complication Associated with Stevens-Johnson Syndrome", Vol. 24, pp. E22-25 (2007)
4229	Claes P., et al., Eur J Intern Med, "Nevirapine-induced TEN and Toxic Hepatitis Treated Successfully with a Combination of IVIG and N-acetylcysteine", Vol. 15, pp. 255-258 (2004)
4230	Chatterjee S., et al., J Postgrad Med, "Nimesulide-induced Hepatitis and TEN", Vol. 54, No. 2, pp. 150-151 (April 2008)
4231	P Sternlieb, RM Robinson, Annals of Intern Med, "Side Effects of Ibuprofen (A commentary on Kantor, et al.)", Vol. 92, No. 4, pp. 569-570 (1980)
4232	TG Kantor, Ann Intern Med, "Ibuprofen", Vol. 91, pp. 877-882 (1979)
4233	Shah AP, Eur Respir J, "Severe Airflow Obstruction and Eosinophilic Lung Disease After Stevens-Johnson Syndrome", Vol. 28, pp. 1276-79 (2006)
4234	de la Reyes, SR., et al., J Adolesc Health Care, "Potential Permanent Respiratory Sequela of Stevens-Johnson Syndrome in an Adolescent", Vol. 6, No. 3, pp. 220-223 (May 1985)
4235	Transcript of the Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee, February 16, 17 and 18, 2005 (Volumes I-III)
4236	Pichler, W.J., Drug Hypersensitivity. Basel, Switzerland: Karger, 2007.
4237	R. William Soller, "Prescription to Over the Counter Switch Criteria," Drug Information Journal, Vol. 36, pp. 309-317 (2002).
4238	R. William Soller, "OTCness," Drug Information Journal, Vol. 32, pp. 555-560 (1998).
4239	Cox, K.L., et al, "Pediatric Liver Transplantations," Journal of Gastroenterology and Hepatology, 14 Supp. ():S61-6 (May 1999)
4240	Pulmonary Complications in Toxic Epidermal Necrolysis: A Prospective Clinical Study. F Lebargy, P Wolkenstein, M Gisselbrecht, JC Roujeau, et al. Intensive Care Med 1997; 23:1237-44
4241	Bronchiolitis Obliterans: A Rare Chronic Pulmonary Complication Associated with Stevens-Johnson Syndrome. A Bakirtas, K Harmanci, M Toyran, et al. Pediatric Dermatol 2007; 24:E22-25
4242	Drug-Associated Acute-Onset Vanishing Bile Duct & SJS in a Child. M Srivastava, A Perez-Atayde, MM Jonas. Gastroenterol 1998; 115:743-6
4243	Strom, B. (Ed.), Pharmacoepidemiology 4th Edition, John Wiley & Sons Ltd. (2005)
4244	"Stevens-Johnson Syndrome: A Disease of Diagnostic and Therapeutic Controversy," U.S. Pharmacist Continuing Education, ACPE Program No. 430-000-01-024-H01, printed from http://www.uspharmacist.com/ce/stevensjohnson/lesson.cfm.

4245	Eikenberry M, et al., Biology of Blood and Marrow Transplantation, "Natural History of Pulmonary Complications in Children after Bone Marrow Transplantation", Vol. 11, No. 1, pp. 56-64 (Jan. 2005)
4246	Mockenhaupt, Maja. Antirheumatic Medication and the Risk for Severe Cutaneous Adverse Reactions (SCAR), ISPE August 2000
4247	Mockenhaupt, Maja, Epidemiology and Causes of Severe Cutaneous Adverse Reactions to Drugs, In Pichler W (Ed.), Drug Hypersensitivity 1st edition, Ch. 2 pp. 18-31, Karger-Verlag (2007)
4248	Reference Manual on Scientific Evidence, 2nd Edition, Federal Judicial Center (2000)
4249	Golitz, L., et al., Pediatric Dermatology, "Bullous Mastocytosis: Diffuse Cutaneous Mastocytosis with Extensive Blisters Mimicking Scalded Skin Syndrome or Erythema Multiforme," Vol. 1, No. 4, pp. 288-94 (April 1984)
4250	Metcalfe, D., J Investig Dermatol, "The Liver, Spleen, and Lymph Nodes in Mastocytosis," Vol. 96, pp. 45S-46S (1991)
4251	Carter, M., et al., *Biology of Mast Cells and the Mastocytosis Syndromes*. In Wolff, K., et al. (Eds), Fitzpatrick's Dermatology in General Medicine 7th Edition, Ch. 150, McGraw-Hill Companies (2008)
4252	Metcalfe, D., et al., *Mastocytosis*. In Goldman, L., et al. (Eds), Cecil Textbook of Medicine 22nd Edition, Ch. 272, Saunders (2004)
4253	Niedoszytko, M., et al., Allergy, "Mastocytosis and insect venom allergy: diagnosis, safety and efficacy of venom immunotherapy," Vol. 64, pp. 1237-45 (2009)
4254	Shiloh-Malawsky, Y., et al., Pediatric Emergency Care, "Mastocytosis: The pediatric emergency physician's perspective," Vol. 19, No. 3, pp. 172-73 (2003)
4255	Alto, W., et al., Amer. Family Physician, "Cutaneous and Systemic Manifestations of Mastocytosis," June 1999
4256	Foxnews.com, "Lawsuit: Children's Motrin Caused Blindness," December 29, 2004
4257	Benichou, J., Statistics in Medicine, "Methods of Adjustment for Estimating the Attributable Risk in Case-Control Studies: A Review," Vol. 10, pp. 1753-73 (1991)
4258	Whitemore, A., Statistics in Medicine, "Statistical Methods for Estimating Attributable Risk from Retrospective Data," Vol. 1, pp. 229-43 (1982)
4259	Coughlin, S., et al., Epidemiologic Reviews, "Attributable Risk Estimation in Case-Control Studies," Vol. 16, No. 1, pp. 51-64 (1994)
4260	Greenland, S., et al., J of Epidemiology, "Conceptual Problems in the Definition and Interpretation of Attributable Fractions," Vol. 128, No. 6, pp. 1185-97 (Dec. 1988)
4261	Bruzzi, P., et al., Am J Epidemiology, "Estimating the Population Attributable Risk for Multiple Risk Factors Using Case-Control Data," Vol. 122, No. 5, pp. 904-14 (1985)
4262	Walter, S., Am J Epidemiology, "Effects of Interaction, Confounding and Observational Error on Attributable Risk Estimation," Vol. 117, No. 5, pp. 598-604 (1983)
4263	Wolfe, M., et al., Arch Intern Med, "Improving Prescription Drug Warnings to Promote Patient Comprehension," Vol. 170, No. 1, pp. 50-56 (2010)
4264	Cox, Jr., L., Risk Analysis, "Probability of Causation and the Attributable Proportion of Risk," Vol. 4, No. 3, pp. 221-30 (1984)
4265	Farthing, P., et al., Oral Diseases, "Mucosal Diseases Series, Number IV, Erythema multiforme," Vol. 11, pp. 261-67 (2005)
4266	Ray, C., et al., Clinical Endocrinology, "Coxsackie B Virus Antibody Responses In Juvenile-Onset Diabetes Mellitus," Vol. 12, pp. 375-78 (1980)
4267	Davidovici, B., et al., IMAJ, "Profile of Acute Generalized Exanthematous Pustulosis in Israel During 2002-2005: Results of the RegiSCAR Study," Vol. 10, pp. 410-12 (2008)
4268	Wogalter, m. (ed.) handbook of warnings (human factors/ergonomics), lawrence erlbaum associates (2006).

4269	Tidy, C., "Stevens-Johnson Syndrome," May 1, 2007, EMIS.
4270	Parrillo, S., et al., "Stevens-Johnson Syndrome," January 23, 2008, Emedicine.
4271	Coggon, D., et al., Epidemiology for the Uninitiated 4th Edition, BMJ Publishing Group (Jan. 1997).
4272	Ward, K., et al., Am J Health-Syst Pharm, "Severe adverse skin reactions to nonsteroidal antiinflammatory drugs: A review of the literature," Vol. 67, pp. 206-13 (2010)
4273	Northridge, M., Am J Public Health, "Annotation: Public Health Methods -- Attributable Risk as a Link between Causality and Public Health Action," Vol. 85, No. 9, pp. 1202-04 (Sept. 1995)
4274	Bianchine, J.et al., Amer. J. Med., "Drugs as Etiologic Factors in SJS," 44:390-405 (1968)
4275	Broadhead, W., et al., Am J of Epid., "The Epidemiologic Evidence for a Relationship between Social Support and Health," Vol. 117, No. 5, pp. 521-37 (1983)
4276	Murri, R., et al., Clinical Infectious Diseases, "Fatal Toxic Epidermolysis Induced by Zidovudine," 23:640-41 (1996)
4277	Elzagallaai, A, et al., Mol Diagn Ther, "In vitro testing for the diagnosis of anticonvulsant hypersensitivity syndrome: a systematic review," 13(5), pp. 313-30 (2009)
4278	Sanchis, et al., J Oral Pathol Med, "Erythema multiforme: diagnosis, clinical manifestations and treatment in a retrospective study of 22 patients," 39: 747–752 (2010)